IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

SECURITY NATIONAL BANK, as Conservator for JMK, a minor child,	No. C11-4017-MWB
Plaintiff,	Sioux City, Iowa January 8, 2014
vs.	7:57 a.m.
ABBOTT LABORATORIES,	Volume 3 of 10
Defendant.	

REDACTED TRANSCRIPT OF TRIAL
BEFORE THE HONORABLE MARK W. BENNETT
UNITED STATES DISTRICT JUDGE, and a jury.

APPEARANCES:

For the Plaintiff:	AMANDA BRANDY VAN WYHE, ESQ. TIMOTHY S. BOTTARO, ESQ. Vriezelaar, Tigges, Edgington, Bottaro, Boden & Ross 613 Pierce Street Sioux City, IA 51102 STEPHEN C. RATHKE, ESQ. ROBERT J. KING, ESQ. Lommen, Abdo, Cole, King & Stageberg 2000 IDS Center 80 South Eighth Street Minneapolis, MN 55402
For the Defendant:	JOHN C. GRAY, ESQ. Heidman Law Firm 1128 Historic 4th Street Sioux City, IA 51102 DANIEL E. REIDY, ESQ. JUNE K. GHEZZI, ESQ. GABRIEL H. SCANNAPIECO, ESQ. KATHRYN L. DORE, ESQ. Jones Day Suite 3500 77 West Wacker Drive Chicago, IL 60601
Also present:	Louise Deitloff Daniel Morrison
Court Reporter:	Shelly Semmler, RMR, CRR 320 Sixth Street Sioux City, IA 51101 (712) 233-3846

(Proceedings reconvened outside the presence of the jury.)

THE COURT: Please be seated. Good morning. Anything on the parties' agenda that you need to take up before we bring the jury in?

MR. RATHKE: No, Your Honor.

THE COURT: Anybody from the defense?

MR. REIDY: No, Your Honor.

THE COURT: Okay. Well, you should all have a order to show cause that I entered this morning, and I wanted to talk to the parties about it but particularly Ms. Ghezzi. Here's my view. I don't want you to have to be concerned about this, although hopefully you're concerned about it, but I don't want to take time away from your trial preparation to deal with this because I don't think that would be fair. So we need to set up a procedure to deal with it because I am going to deal with it. And so here's what I've outlined, and I want to get the reaction to it.

Seems to me you have two choices: You can either agree that a substantial portion of the objections that you made in the depositions lacked both a legal and factual basis, or you cannot agree with that. And if you agree with it, then I would make a finding that a substantial portion of the objections lacked a legal and factual basis, and then we would have a hearing to talk about what the potential sanctions are and what

the appropriate sanction could be.

If you take the position that all of the objections or a substantial portion of the objections had a good-faith legal or factual basis, then I'm going to require you, Miss Ghezzi, to indicate for each objection you've made what the factual basis is.

And so, for example, when you make the frequent virtually -- virtually on every page, I mean, hundreds and hundreds of object to the form, you're going to have to indicate what you meant by that. And let me ask you right now, what do you -- what do you -- what do you consider that objection to include when you object to the form?

MS. GHEZZI: Object to the form is anything in the question that is compound or vague or ambiguous that can be remedied at the time of the deposition so that you don't waive the objection at trial if the deposition is used at trial.

THE COURT: Anything else it includes in your view?

MS. GHEZZI: Well, I mean, Your Honor, I'd have to look at the -- I'd have to look at the --

THE COURT: Well, you make the objection so frequently, so you must know what it includes.

MS. GHEZZI: Well, you know, I mean, Your Honor, I've been practicing for 31 years.

THE COURT: I don't care about that.

MS. GHEZZI: When I was -- well, when I was trained --

I started my career at Sidley and Austin when I was trained as an associate.

THE COURT: Yeah, I don't care about any of that. You just tell me what you think it means.

MS. GHEZZI: Okay.

THE COURT: Object to the form, I want to know everything you think that means.

MS. GHEZZI: Your Honor, I haven't given it a lot of thought right now. It's --

THE COURT: Well, I'm asking you to tell me what you think it means. You certainly --

MS. GHEZZI: It's a pr --

THE COURT: -- are very free to use it in depositions. I mean, that's your mantra.

MS. GHEZZI: I know it when I hear it. If there's a question and there's an improper -- it's an improper question because it c -- because it's compound or because it is vague or ambiguous or lack --

THE COURT: Actually --

MS. GHEZZI: -- or lack of foundation.

THE COURT: -- there's case law saying that if it's vague or ambiguous that's not a proper objection to the form. But anyway, keep going.

MS. GHEZZI: Well, I'm sorry, Your Honor, but that was my training, that if it's --

THE COURT: I don't care if it was your training or not. I want to know what you understand it to be.

MS. GHEZZI: That's my understanding.

THE COURT: Anything else that is included in the objection to form?

MS. GHEZZI: Anything -- anything that can be remedied -- anything that can be remedied at the time of the deposition so that you do not waive the objection if the deposition is used at a hearing or trial.

THE COURT: That's your definition.

MS. GHEZZI: That has to do with the form of the question, yes, Your Honor, that's my definition.

THE COURT: And what's your legal basis for objecting to the form of the question?

MS. GHEZZI: The -- I believe the federal rules allow depo -- allows objections to the form of the question.

THE COURT: Where in the federal rules do they allow that?

MS. GHEZZI: Your Honor, I haven't -- I don't know. I don't have the book. I haven't prepared for this right now. I've been preparing most of the night and the early morning hours for the trial.

THE COURT: Okay. Now, if you decide to contest my preliminary opinion that a substantial majority of your objections lacked a good-faith basis in law and fact, then you

are going to have to give me the good-faith basis. And you have to do that personally because you're the one that made the objection. So you can't have associates researching it, have other lawyers in your firm or legal assistants or anyone else read it and suggest what the basis might be for your objection. You have to do it personally. Doesn't that make sense, because you're the one that made the objection? You have to personally indicate what the basis for that objection is because you're the one that made it. Well, that's what I'm ordering you to do. And there will be very severe consequences if you seek any help in doing that because I need to know what your good-faith basis was at the time you made it, and you are the only one that would know that.

So you are not allowed to -- in terms of responding to the order to show cause, if you elect to go through every single objection you made and provide what you believe is your good-faith factual basis for it, you need to do that yourself without any outside assistance from any lawyer, legal assistant, human being, legal research service. It just has to be what you were thinking at the time, what your basis was at the time, and only you are allowed to do that.

Now, once you do that, the easiest way to do it might be to go through every deposition and write down leading or compound or whatever it is that you think was objectionable. You can obviously have somebody else transcribe that. I'm not

concerned about the transcription of it, but I'm concerned about that it comes solely from you because you're the one that made the objection. Do you have any questions about that?

MS. GHEZZI: I don't have any questions about it.

THE COURT: Okay. Is there anything about it you don't understand?

MS. GHEZZI: There isn't anything about it I don't understand.

THE COURT: Okay. Is there a better way to approach this that you're aware of? Or would you like some time to think about a better way?

MS. GHEZZI: Yeah, Your Honor, I mean, yeah, I think there is, but I'd like to -- I definitely would like some time to think about it.

THE COURT: Okay. But just give me what you're thinking might be a better way to do it.

MS. GHEZZI: Well, I don't know that going through seven or eight depositions and showing you what my -- you know, why I do it for whatever question, if it's leading, I think if maybe a representative deposition I could do it. I mean, I can do whatever you order obviously. You're the judge, but I'm thinking that so you can see what the thought process is and the quality of the questions that we're dealing with and what my thought process is, what the basis of the objection is. Happy to do it. I mean, I just don't know that doing it for --

THE COURT: Every -- yeah. That has some appeal to me. Okay. At least we could start with that, and that may be sufficient, and that may actually resolve the matter. But that makes some sense.

MS. GHEZZI: Okay.

THE COURT: As long as I get to pick which deposition.

MS. GHEZZI: Sure.

THE COURT: Okay?

MS. GHEZZI: You're the judge.

THE COURT: Yeah. No, no, no, that seems very reasonable and less onerous. So here's what I'd like to do. I'd like -- well, why don't you let me know by the end of the trial -- I'm pretty confident you're not going to concede that you made improper objections. But in the unlikelihood that you review it and decide that, let me know by the end of the trial, and then if you don't do that, we'll come up with a time frame for you to go through one or maybe two depositions and do what I've indicated, and we'll set that -- we'll set a time frame, but I'm obviously going to defer to you as to how much time you need to do that.

MS. GHEZZI: Yeah, and, Your Honor, I do have another trial starting on March 10 in another state, and, you know . . .

THE COURT: Sure.

MS. GHEZZI: Haven't been able to prepare for that because of preparing for this so . . .

THE COURT: Yeah.

MS. GHEZZI: Happy to do it. And if -- you know, obviously if I look at something and it's -- I don't agree that -- you know, I was wrong to do it, I'll write withdrawn or whatever, but, I mean, for the most part I tend to do how I was trained which was --

THE COURT: Yeah. Well, that's the sad part, that you were trained to make so many objections like that. And I notice when I read Scannapieco's defending of a deposition, he learned well from you. And you know what? The only reason my order to show cause doesn't include him is because he's a young associate and I assume he was trained to do it that way. I don't think it's a proper way to take a deposition. So why don't you let me know at the end of the trial what you want to do, and then we'll come up with a time frame for you to do one, probably two depositions; okay?

MS. GHEZZI: Sure.

THE COURT: Okay.

MS. GHEZZI: Thank you, Your Honor.

THE COURT: Anything the plaintiff wants to add to that?

MR. RATHKE: No, Your Honor.

THE COURT: Okay. Anything we need to take up now before 8:30?

MR. RATHKE: No, Your Honor.

MR. REIDY: No, Your Honor.

THE COURT: How much longer of cross do you think you have for Dr. Jason? And I'm not trying to rush you.

MS. GHEZZI: No. I know, Your Honor.

THE COURT: Just curious.

MS. GHEZZI: No. I know. You know, I -- I'm hoping -- I'm hoping under an hour. I'm hoping I can do it between 30 minutes and 45.

THE COURT: Oh, okay.

MS. GHEZZI: Okay?

THE COURT: Sure.

MS. GHEZZI: I'm hoping. Fingers crossed.

THE COURT: Sure. No, no, no. That's a qualified -- you bet. And given how she responds, it's pretty hard to estimate the time, so I appreciate that.

MR. BOTTARO: I'm just conferring with counsel.

THE COURT: Okay. Anything you need me for?

MS. VAN WYHE: Your Honor?

THE COURT: Yes.

MS. VAN WYHE: These are the copies and an electronic copy of the depositions that you don't have.

THE COURT: Okay. Thank you.

MS. VAN WYHE: I noted the ones I think you already have, but I have copies of the ones you --

THE COURT: No, I already have those. Okay. Great.

Thank you. Okay. We'll see you back here at 8:30.

(Recess at 8:10 a.m.)

THE COURT: Ready to have the jury brought in?

MR. RATHKE: Yes, Your Honor.

(The jury entered the courtroom.)

THE COURT: Good morning. Please be seated. Thank you.

And, jurors, you will recall that Ms. Ghezzi was cross-examining Dr. Jason, and that's where we're going to start up.

So any time you're ready, Miss Ghezzi.

MS. GHEZZI: Thank you, Judge. If you give me just a minute to get my papers in order here.

THE COURT: Sure.

JANINE JASON, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

CONTINUED CROSS-EXAMINATION

BY MS. GHEZZI:

Q. Good morning, Dr. Jason.

A. Morning.

Q. You haven't spoken to any of your counsel on any substantive matter since you were on the stand yesterday, have you?

A. No.

Q. Okay. I'd like to ask you some questions about infectious dose that you talked about and incubation period. On direct --

and these are from my notes, so they might not be completely verbatim, but I think you said that the time between when the bacteria enters the body and when the person first shows signs of dis -- or symptoms of disease is your definition of incubation period; is that correct?

A. Yes.

Q. Okay. And you said that you were relying in part on the Mittal study. That's the scientist's name, Mittal study?

A. Correct.

Q. Okay. And that when six hours -- after six hours of being inoculated -- not inoculated but gavaged, fed with the bacteria, E. sak bacteria, that the mice pups showed no activity; correct?

A. No, that is not correct.

Q. Okay. I wrote that down that you said that, but that's okay. Okay. So after six hours you said that there was bacteria in the blood.

A. There was bacteria found in the organs including the brain and the liver.

Q. Okay. And that would be in the blood, right, in the tissues?

A. In the -- well, there's a difference between the blood and the tissues. They actually found it in the tissue of those organs.

Q. Okay. Okay. And then you said within 12 hours they were laying with their feet up in the air; correct?

A. They had their -- only the ones with the OmpA on the surface.
Q. They were laying with their feet up in the air.
A. They had their feet in the air, yes.
Q. And you suggested --
A. Oh, I'm sorry. That was at 12 hours.
Q. That's what I said, 12 hours.
A. Yes.
Q. We're on the same page. And you suggested that Abbott's expert, Dr. Shulman, who you know to be the head of pediatric infectious disease at the Lurie Children's Memorial Hospital in Chicago, did not know how to read the study; right?
A. I said that that portion appeared to have been misinterpreted, yes.
Q. Okay. I'd like to have you look at that with me.
MS. GHEZZI: And, Your Honor, this is an article. It's not evidence, so I'm going to -- so you can see it.
THE COURT: Okay. Thank you.
MS. GHEZZI: I'm going to put it on and then make sure that's blacked out. I don't know if you can see that, Your Honor, or not. We're talking about this.
THE COURT: Yes. Thank you.
MS. GHEZZI: You're welcome, Your Honor.
BY MS. GHEZZI:
Q. Okay. Now, Dr. Jason, let's look at the 12-hour column.

Do you see that?
A. I do.
Q. Okay. And what this table does, it's an activity score for the animals, for the mice pups, after they have been given the bacteria; correct?
A. Correct.
Q. All right. And it shows that for the first line there, what you were talking about, OmpA, E. sakazakii -- I'm sorry. There's a plus sign after that, OmpA+, ES, that after six hours their activity level was normal. Do you see that?
A. Yes.
Q. Okay. And that would mean that even in these two-day-old mice pups that there was no disease process; correct?
A. That is not correct.
Q. Okay.
A. It takes a while for there to be an impact on activity after the bacteria has spread to, for instance, the brain.
Q. Let me rephrase that. There was no symptom of disease.
A. There was no gross symptom of disease. Realize this is not like an infant where you have things like irritability. On their score they did not pick up this particular symptom at six hours.
Q. Okay. So the way these scientists were doing it who were actually doing it in the study, they recorded it as normal activity.

A. Correct, in regard to what they're measuring.
Q. Exactly. And what they're measuring, because they do this all the time with mice pups, is activity level, and that's how you determine what the disease process is if it's there or not there; isn't that correct?
A. It is what they do all the time, and it's because of the limitations of what you can look at in a mice pup. So yes, this is the standard approach.
Q. And by the way, you've never done any experiment on mice pups, have you?
A. I've done immune experiments on mice pups but not this sort of experiment.
Q. You've never done any bacterial experiments on mice pups.
A. No.
Q. Okay. And then -- and let's just go -- and then at the 12-hour period, the score goes down to 4, plus or minus 0. See that?
A. Correct.
Q. Okay. And on the slide -- I'm sorry. In the article -- I wish I could read this better, but it says 4, turns upright; right?
A. No, it says turns upright less than 5 seconds.
Q. Turns upright in less than 5 seconds.
A. So in other words, they're over, and it takes them a while to get back up.

Q. Yeah. But what it shows is that they're on their backs; right? The way they start this slide -- I mean -- I'm sorry -- the way they start this study is they put their animal -- they put the animals on their back, and then they see how long it takes them to right themselves, to get up on their feet.
A. Correct.
Q. Okay. So at 12 hours right there -- woops.
A. It's the next one up.
Q. Yeah. I didn't mean to do that actually. At 12 hours -- I don't know why that keeps going on. Their activity level says they turn upright in less than 5 seconds; correct?
A. Well, I think our emphasis is different. It takes them some time to get upright.
Q. Okay.
A. So in other words, they don't pop back up the way a normal pup would do.
Q. Okay. But the fact of the matter is is that at 12 hours they were not lying with their feet up in the air, were they?
A. They are with their feet up in the air, and it takes them a while to get up. These are not behaving normally by 12 hours.
Q. But, Dr. Jason, they're put with their feet up in the air. They start with their feet up in the air and then --
A. Well --
Q. Excuse me. Let me finish, please. They start with their feet up in the air. They're turned on their backs, and their

feet are up in the air, and then the scientists are trying to discover what the activity level is in these 2-day-old mice pups after 12 hours, and they right themselves in less than 5 seconds.

A. Which is not normal. And if you look at 12 hours, you see that there's a progression. This is not normal behavior, and the symptoms begin by 12 hours. Again --

Q. Okay.

A. -- they can't measure very subtle things like irritability and feeding issues. They have a gross measure of something being wrong, and in this case it's that a normal newborn pup who normally would pop right up stays for up to five seconds lying on their back before they can get up.

Q. Well, it doesn't stay for up to -- well, it says less than five seconds. It could be one second. It could be two seconds. It could be a half a second. What they're measuring here is a five second. It's less than five seconds.

A. And it is not normal to take --

Q. It could be less than a second.

A. The reason they have this measure is that's not normal activity.

Q. Dr. Jason, I wish you would, you know, try and answer my question. When it says less than five seconds, it can be less than a second; correct?

A. I don't know if it's that accurate, but it is not

immediate.
Q. Well --
A. I don't know that they can measure it down to a second. They know on their time that it takes -- I think we're not disagreeing --
THE COURT: Dr. Jason, that actually wasn't the question counsel asked you, so try and listen to the question she asks, and try and answer it. Thank you.
Q. Okay. Let's look at the next column, 24 hours. At the 24-hour period is when the mouse or the mice pups had no activity, right, coma/death, after 24 hours?
A. By twenty --
Q. Okay. Is that what it says?
A. Okay. At 24 hours the average -- the average activity of the mice was that they were comatose or dead by 24 hours.
Q. Right, by 24 hours. Now, how much does a two-day-old mice pup weigh?
A. I don't know exactly.
Q. Have you ever weighed a two-day-old mice pup?
A. No, I haven't.
Q. Do you know how heavy five grams is?
A. Yes.
Q. Okay. Is it about the weight of an empty envelope, a little regular letter envelope, about five grams?
A. I don't have a direct comparison.

Q. Okay. The baby in this case, Jeanine Kunkel, weighed over 2,200 grams; right?
A. Correct.
Q. And there's a correlation between inoculation and the size of humans; correct?
A. Could you clarify that question?
Q. There is a correlation between the bacteria load and the size of a human, any human, a baby, an adult.
A. Are we talking about cronobacter? Are we talking about -- what are we -- what organism are we talking about?
Q. Whatever you know about. I assume --
A. It varies from organism to organism.
Q. But you've heard of that, right, that it depends on the size of the --
A. That is a potential parameter. In the case of C. sak, we know that very low doses in an infant can cause infection.
Q. Yeah, let's talk about that. You said -- you said in your direct testimony that the Mittal study used very small amounts of this OmpA+; right?
A. Correct.
Q. And you said it was between 100 and 1,000 cells; correct?
A. He found that as low as a hundred cells could have infectivity, yes.
Q. Okay. Now, I want you to look at the page right above that chart if you would. And what it says there is infection with 10^4

CFU of OmpA+ ES induced a steady increase in the disease severity of the animals which ended in a moribund state at 48 hours post-infection. Do you see that?

A. No, but I recall that sentence.

Q. Okay. And 10^4 is how much?

A. 10^4 is 10,000.

Q. Right. That's not a hundred, is it?

A. No, but I've actually contacted this author, and also he has --

Q. Okay. Dr. Jason --

A. -- I believe elsewhere in this publication said he did get infectivity as low as t -- as --

Q. Okay. This is the activity level that says -- I mean -- I'm sorry. This is the article that you're relying on, and 10^4 is 10,000 cells; right?

A. This is not the only article I'm relying on, and as I say, it is not the article alone, but it's also the communications with this author, his other research that he will cite. And I think if I read this all the way through in this very article he may point out that as low -- with that low of dose he gets something, but I'd have to read through the specific article then.

Q. Okay. Well, I don't think it's in there, but, I mean, you know . . .

THE COURT: Now that's testifying.

MS. GHEZZI: Okay. I'll withdraw that statement, Your Honor.

THE COURT: Okay. Thank you.

Q. And then I want you to go down to the next piece right there. Infection with ten -- I'm sorry. It's right here, Dr. Jason. I'm going to write that on -- I'm going to underline that. Do you see it? Now you probably -- it's probably worse. I'll take it off. Do you see where I am?

A. I do, yes.

Q. Okay. I'm going to take it off so you can actually read it. Okay. And there it says that ES -- this OmpA+ ES induced a steady increase in the disease severity injected -- I'm sorry. That's bad -- disease severity in the animals which ended in a moribund state at 48 hours and then infection with 10^5 CFU of this bacteria induced the disease severity within 16 hours which they didn't put in the chart below, but it says within 16 hours; right?

A. Correct.

Q. And 10^5 is 100,000 CFUs; right?

A. Correct.

Q. And CFU for the benefit of the jury is what?

A. It's colony forming units.

Q. And a colony forming unit is a cell.

A. Correct.

Q. Okay. So what this study shows is not that it took 100 or

a thousand OmpA+ E. sakazakii bacteria to create this activity level in these 2-day-old, 5-gram mice pups but that it took 10,000 and then 100,000 cells; right?

A. You're focusing on a phrase. An infant could have gotten that dose in a clump, and the point is that they did become symptomatic that quickly.

MS. GHEZZI: Judge, I move to strike it. Nonresponsive.

THE COURT: Sustained. Jury's advised to disregard the last answer of Dr. Jason.

Q. Now, let's go to the second source I think you mentioned yesterday that you were relying on. It was a case report, the CDC case report; correct?

A. I don't know. What is that? I don't know what we're talking about.

Q. When we were talking about the incubation period and you said you relied on some studies and I said is that all and you said no, I relied on a case report from the CDC. Remember that?

A. What I -- I don't recall that. I did rely on data from two infants that became infected in Mexico with a U.S. product.

Q. Okay.

A. And I think I did mention that there were several other cases that occurred less than 24 hours after receiving the first powdered formula.

Q. Okay. You testified that there could be an incubation

period in an infant of 7 hours; right?
A. I said that there was one invasive case where the PIF had been taken at approximately seven hours before. But that -- I hope I did not suggest that was my sole source of that --
Q. Okay. I thought you said that there was this one case report, but let's talk about that one case report because I believe that you -- that's what you mentioned I think in your report and at the time of your deposition. So let's talk about that one. That involved an eight-month-old baby; right?
A. Are we talking about the Mexican cases?
Q. We're talking -- no, a California case, eight-month-old baby who had powdered --
A. I would say -- yeah, I would not --
Q. Excuse me. Can I finish my qu --
A. Sure.
Q. Thank you. It involved an eight-month-old baby who was fed powdered infant formula seven hours before he showed signs of some infection. Do you remember that?
A. I know the case you're referring to, but that is not the case I relied on in my opinion.
Q. Okay. Well, you -- it was in your report; right?
A. It is one of the cases. I mean, when you --
Q. Okay. Let's talk about it.
MR. RATHKE: Your Honor, I'm going to object.
THE COURT: You need to put on your microphone.

MR. RATHKE: My objection is that Miss Ghezzi is continually interrupting and in that last question and answer did interrupt the witness when she was trying to answer the question.

THE COURT: Well, they both interrupt each other. We've already tried to address it, and I'll just ask both sides again. Dr. Jason, you let Miss Ghezzi finish her question, and then you try and answer the question she asks. And likewise Miss Ghezzi will try not to interrupt you. But if you interrupt her, then she's got a right to interrupt you. So that's what -- that's where kind of the problem lies.

BY MS. GHEZZI:

Q. So, Dr. Jason, you -- you have stated that the incubation period for E. sak in an infant can be seven hours, and you've also testified -- I'm sorry. You've also -- well, you also hold the opinion that it could be eight months; right?

A. We would need to define what type of infection, but yes, there have been cases that -- well, I'm not sure what the basis of your saying that is. When we talk about cases that occur eight months, I would have to go back and see if that's eight months after their first feeding of PIF.

Q. Yeah. And it is.

A. Okay. In that --

Q. So let's talk about that.

A. In that case, yes, that -- well, let's t -- yeah, I'm not

sure --
Q. Let me ask a question.
A. -- what exactly you're asking.
Q. Okay. So this is the eight-month-old baby from California, and this baby had been fed powdered infant formula from birth. And then he was fed it throughout his eight months. And in the normal course, five, six, seven, eight months, he was also given other foods. Remember this one?
A. I do. Actually this is not one I included in my paper because there was other feeding and he had other underlying disorders. So I don't remember him all that well.
Q. Well, this is something that you talked about in your report, though. You listed him in your report. This is what you talked about in an incubation period; right?
A. I did not include him in my analyses, but in the appendices where I described cases, I would have to look, but I could well have included him.
Q. So this is a baby who was fed powdered infant formula from his -- from birth for eight months, and it was your conclusion that the incubation period could be seven hours or it could be eight months because he had powdered infant formula when he was first born, his first -- the first powdered infant formula feeding at birth, and then the last infant formula feeding before symptoms occurred was seven hours so the incubation -- the possible incubation period could be as long as eight months;

right?
A. I would hope I did not give that impression. If I had that in my report, it was probably in the context of explaining how difficult it is to define incubation period in these cases where infants get repeated feedings of powdered infant formula because you don't know which of those feedings was contaminated.
Q. Yeah.
A. So hopefully that's the context that it was in. Otherwise I apologize if I was misleading.
Q. Okay. Well, in that -- in this particular case, the child who was still an infant had been fed -- when he could eat food, he'd been fed vegetables, soups, bananas, pasta, corn, and tortillas; right?
A. As I say, this is not a case I included in my opinion.
Q. No, exactly. You -- no, you included it in your report in the case, in your opinion, not --
A. I included it in terms of -- I'm sorry. What can I say?
Q. Okay. But you didn't consider -- when you were looking at it for your report, not your manuscript, for your report in this case, you didn't consider any of these foods as possible sources of the child's E. sak infection when you were using it to support your opinion in this case about the seven hours -- the seven hours incubation time, did you?
A. I did not specifically say the incubation time was seven hours for this organism. I was pointing out that the range of

incubation time for some virulent C. sak can be very short, in a matter of hours, not days.
Q. Okay.
A. This particular case I described -- likely I described in my appendix because I tried to describe every case that somebody doing research might be interested in.
Q. Dr. Jason, you continue to talk about your paper. I'm talking --
A. Because you brought it up.
Q. I know. But I'm asking you about your report. We already said it wasn't -- you know, it --
MS. GHEZZI: Strike that, Your Honor, please, or Miss Court Reporter.
Q. In your report on paragraph 187 you say a CDC note unrelated to Jeanine Kunkel suggests cronobacter's incubation period sometimes may be as short as a matter of hours, and this is the case you cite; correct?
A. Yes, I do.
Q. Okay. Now, you don't put the entire CDC note in your report, but we looked at it, and the entire CDC report in there --
MR. RATHKE: Your Honor, I'm going to object to counsel testifying.
THE COURT: Well, this was prefacing for a question.
Q. So the -- in that report -- and I'm sure you read the whole

thing -- that the CDC went out or had a local agency go out and surveyed the home, and there were -- this child was living in a bedroom that had multiple -- multiple adults like six adults and other children in the same room; right?

A. Correct. I just want to emphasize that this case is not the basis of my opinion on incubation period.

Q. Well, it's in your report as substantiating your incubation period testimony.

A. In the context of that case, CDC also considered that as potentially a sign that the incubation period could be that. They as well pointed out that the infant had other food, and the context is how difficult it is to determine incubation period in this kind of setting.

Q. Right, in the --

A. Which is why when they have other foods you really don't know what's going on.

Q. Well, let's see what else was going on. In this case the mother was cleaning the water jugs. She made the bottles from a water jug. And she refilled with fresh water from the water station, and she cleaned the jugs by adding soap and water and pinto beans to the jug and agitating it, and that's how she cleaned the jug. Did you remember that?

A. I agree that that is not a clean case which is why I did not include it in terms of my opinion.

Q. Well, it's not a clean case. It's not a clean case because

it shows that there are all sorts of other environmental issues in that family and in that home environment that could have infected this baby's food or this baby, correct, or --

A. No, that is not correct. The infant had had other foods that were not sterile that certainly could have contributed. We don't know what kind of cronobacter that infant had. We don't know if it was a virulent form. But we do know that that infant indeed was exposed to other food sources that could potentially have had cronobacter.

Q. Right.

A. Not necessarily around the house but other food unlike the younger infants who have nothing but formulas.

Q. But there is -- but, but, there -- there are bacteria in those other foods, right, that aren't sterile including what she ate?

A. Correct.

Q. Vegetables --

A. Correct.

Q. -- soups, bananas --

A. Which is why --

Q. Excuse me, excuse me. Bananas, pasta, corn, and tortillas; correct?

A. Correct.

Q. And if those are in your house and there can be bacteria in there and they are bacteria -- and there are bacteria in there,

there can be cross-contamination; right?
A. I disagree. The likelihood of cross-contamination and those materials infecting an infant is extremely low.
Q. And that's your opinion.
A. If we are talking about more likely than not, I would say that is less likely by far than it being from what the infant was actually fed.
Q. And that's your opinion.
A. That is my opinion.
Q. Okay. But you didn't consider any of these foods as a possible source of the child's E. sak when you were using this case to support your opinion in your report; right? You didn't take it out of the report. It wasn't good enough to put in your article, but you put it in the report in this case to support your opinion in this case.
MR. RATHKE: Your Honor, I object as multiple questions.
MS. GHEZZI: I'll rephrase it, Your Honor.
THE COURT: Okay. Thank you.
MS. GHEZZI: Uh-huh.
BY MS. GHEZZI:
Q. You didn't -- you kept it -- you put it in -- that was terrible. I'm going to start over.
You put it in this report to support your theory about very low hours of incubation between bacteria that you say is in

powdered infant formula and the onset of symptoms; right?
A. If that is how you read it, I would have taken it out of my report. My recollection was I put it in there in terms of describing how difficult it is to determine how low -- how short the period could be. So hopefully I have corrected whatever confusion.
Q. Okay. Now, in your article --
MS. GHEZZI: One moment, Your Honor.
Q. There were limitations to your analysis in your article, and you mentioned what they were. And we talked about one of them yesterday. Do you remember that?
A. Yes.
Q. Okay. And another one that you mentioned in your article as being a limitation of your analyses was that reporting may be biased in regard to case characteristics and information collected; correct?
A. Correct.
Q. And another one of your limitations that you noted was that information concerning feeding, preparation, and storage techniques was not provided in response to standardized questionnaires and, therefore, is incomplete and varies between records; correct?
A. Correct.
Q. And we talked about this yesterday. I'm not going to spend a lot of time on it. But in order to get your paper published,

you had to submit it and get reviewers' comments; right?
A. Correct.
Q. Okay. And one of the criticisms indicated that she, meaning the author, does not address the point that 16 percent of infants in the 2003 and 2008 time period were not exposed to powdered infant formula and, therefore, that other vehicles must exist. Readers will appreciate a more balanced discussion of this. That was a reviewer's comment; right?
A. And that was one that I responded to.
Q. Exactly. And in order to get your paper published, you had to actually do a supplement to it in order --
A. Oh -- I'm sorry. Finish.
Q. -- in order to show all the cases that you had excluded from your analysis; isn't that correct?
A. That is absolutely incorrect.
Q. Okay.
A. And, in fact, I did not have to change anything in response to -- when reviewers review articles, they can make suggestions. They don't require changes. And as I recall, I didn't make a whole lot of change except telling that reviewer and explaining what I did. Appendices I had ready to go. I wanted them as part of the primary article because to me they were one of the most important things.
Q. Okay.
A. That way other researchers could use them. I had a

3,000-word limit, and so what we agreed was I could go ahead and put all that in as appendices.
Q. Okay.
A. That was me proactively. That was not in any sense a requirement.
Q. Okay.
A. They would have been glad to have published it without that.
Q. Well, okay. I'll take your word for it.
In your supplement you talked about limitations to microbiological testing in connection with these kinds of cases; correct?
A. Yes.
Q. Okay. And one of them was, speaking of the environment in which the baby is found, microbiologic and/or environmental testing was often not done and, when done, information concerning the testing was often absent, incomplete, or unclear; correct?
A. Correct.
Q. Excuse me. I apologize for that.
And then you also say product testing, when done, was often not of material from an unopened -- unopened containers. That's not the case here, is it?
A. No, it is not.
Q. And you said product testing, when done, often used a

sample size and/or culture techniques not consistent with FDA or CDC protocols; right?
A. Correct.
Q. And that's not what happened in this case, is it?
A. Are we talking about end product testing?
Q. We're talking about product testing, product testing, when you're testing the product that the baby ate, CDC, FDA, whatever testing you're talking about.
A. I'm going to leave that one to the other experts.
Q. Well, you wrote it here. You put it --
A. Are we talking about -- you just asked me about this particular case.
Q. No. I'm asking -- oh, I'm sorry. You're right. But when you wrote it here, you were talking about when you're looking at case reports and you're doing an analysis of a case, this is something that is a limitation, and in this case it's not a limitation; right?
A. The appendices were not limitations. I wanted to give additional information. That does not affect any of my analyses.
Q. Okay. I think we're talking past each other, but let me try and clarify. You write above this that there are a number of limitations that should be considered in interpreting microbiologic testing related to cases of invasive cronobacter infection, and these include the following.

A. So that is my -- my caution to the reader to be aware.
Q. Right.
A. That is not a limitation of my study.
Q. No. That's fine. That's what -- you're telling them that that is a limitation.
A. Correct.
Q. And so what didn't happen in this case is that the product that was tested was not -- was not a sample size or culture technique not consistent with FDA or CDC protocols.
A. And I'm deferring in terms of this specific case to the other specialists, the other experts. You asked me --
Q. Okay.
A. -- if that was followed. I'll let them answer.
Q. Okay. Well, the FDA follows its own protocols, right, when it tests? Would you assume it does?
A. I presume it does.
Q. And the CDC follows its own protocols when it tests?
A. Correct.
Q. Okay. And then it says sometimes the testing was not done at a laboratory experienced in isolating the organism from nonclinical, dry, stressed samples and always assumed a homogeneous distribution of contamination. Now, that doesn't relate to the FDA testing of the infant formula from the batch at issue in this case; correct?
A. Again, I'm going to leave that to the other experts.

Q. Okay. And you also said testing often did not include all products and materials fed to the infant. And certainly that didn't happen here. The baby had had between 68 and 80 feedings before she had her 27 grams of powdered infant formula feedings; right?
A. Could you word that another way?
Q. The baby had a lot of other feedings that weren't tested in this case.
A. She had a number of feedings of sterile, ready-to-feed formula that were not tested, yes.
Q. Yeah, but it's not sterile once it's opened to the environment; right?
A. It may or may not be.
Q. Okay. So it may not be sterile, and none of that was tested here; right?
A. It was not tested.
Q. Okay. And when -- the material remaining in the can used by the infant, the amount was often insufficient for adequate analysis, and that didn't happen in this case either, did it?
A. I'll leave that to the other experts.
Q. Okay. And then you say as a limitation of microbiological testing, when the lot was tested, the production time in relation to the can in question was not noted. It does not appear that attempts were made to test product that approximated the production time of the powdered infant formula fed to the

infant, and that's not this case either, is it?
A. Again, I'm going to leave that to the other experts.
Q. Okay. So when you were doing your -- when you were coming to your conclusions and you -- in this case and you were concluding that there was powdered infant formula in the can -- I'm sorry, that there was E. sakazakii in the can of powdered infant formula that was fed to Jeanine Kunkel --
MS. GHEZZI: That's a terrible question, Your Honor. Can I start over? Let me start over.
Q. When you were doing your report -- I mean when you were making your conclusions in this case, you reviewed the testing results of the FDA and the CDC; correct?
A. Correct.
Q. Okay. And you did that because you wanted to see whether or not the tests were positive; right?
A. And what was done, yes.
Q. Okay. Because if the tests were positive that the FDA and the CDC had done, then you could say, you know, it is more likely than not that the powder -- that the powder that the infant got contained E. sak. You would say that; right?
A. I say that anyway, yes.
Q. You do say that anyway. And all the testing was negative.
A. Correct.
Q. Okay. And so when you were looking at the testing results of the FDA according to see whether or not there were any

limitations of that testing, did you, in fact, go back and see what the production time was in relation to the can in question?
A. I would have to go back and look at my notes.
Q. And are you aware that the can in question was tested -- that the can in -- that the can in question was tested along with 7 -- 16 other cans that were made within 120 seconds of that can? Are you aware of that?
A. Yes.
Q. Okay. Okay. Now, the federal government investigates instances of E. sakazakii infections; right?
A. Pardon? What was that?
Q. The federal government, the CDC, investigates instances of E. sakazakii infection in infants; right?
A. I don't know that it investigates all cases. It tries to investigate them either itself or in collaboration with a local health department.
Q. Okay. And when it does in collaboration with a local health department, it looks for sources of infection other than infant formula, does it not?
A. Yes.
Q. Okay. And it tries to test potential environmental sources in the home environment; correct?
A. Correct.
Q. And when it tests the kitchen, if it's allowed to go in and test the kitchen instead of the county, it tests in the kitchen

the floor, the refrigerator where the formula is stored, cabinets where the bottles are stored, the sink, the dish rack, the sponges, the towels, the utensils used, the counters, and the drains; correct?

A. I don't know that CDC has a standard protocol. They're -- they're -- various cases had things recommended, but I don't know if it's a standardized protocol.

Q. They have a standard questionnaire.

A. They do have a standard questionnaire.

Q. Okay. And so they tell people that this is the kind of thing that they want tested?

A. Exactly, yes.

Q. Okay. So all of those areas that I just mentioned are potential sources of contamination in the eyes of the CDC; right? That's why they want them tested.

A. Well, but contamination can go either way, from powdered -- from powdered formula to something else or vice versa. But yes, those are all areas they look at.

Q. Okay. And they will sometimes sample areas where the infant slept; right?

A. I'd have to go back and see if they've done that.

Q. Well, they certainly sample areas where the child had spent time in the home; right?

A. I was thinking through cases. I don't recall. They prob -- maybe -- from what you're saying, I assume they've done

that in one case or another. I don't recall that as a routine.
Q. Well, sometimes they will sample the areas where the baby sleeps and where the baby has been fed; right?
A. Certainly where the baby has been fed. And I'll take your word that there must have been some cases that make you say that.
Q. Yeah. And sometimes they have sampled things like the baby's toys and a pacifier.
A. Correct.
Q. And they -- and E. sakazakii has been found on a baby's pacifier; correct?
A. There was a single case; and, of course, one question is was that contaminated from the same source as the baby or not. And it's no way to sort that out.
Q. Well, you say there was a single case. I mean, it's reported in one that you looked at; correct?
A. One case that I know of, yes.
Q. Okay. And you would agree that looking at all potential sources absolutely needs to be done; right?
A. Within reason. I would not do a source -- facilities and resources are finite, so absolutely. And let me give an example. In the early cases --
MS. GHEZZI: Your Honor, I'm going to have to interrupt her for the narrative. She just answered the question.

THE COURT: Yeah. You need to try and answer the question directly asked of you and not volunteer additional information.

BY MS. GHEZZI:

Q. So let's talk about when you were on direct several days ago, I think -- well, even maybe yesterday it was -- you were asked about you could rule out certain areas in the home as not being the source here; correct?

A. Correct.

Q. All right. And the baby spent a couple of days at St. Luke's Hospital, didn't she?

A. Yes.

Q. And no one tested the hospital or the hospital environment or the people who came in contact with her on the hospital staff for E. sak, did they?

A. They did not.

Q. And there was no testing of the single-use bottles and nipples that were used at home to feed Jeanine Kunkel between April 17 and April 21; right?

A. I doubt those were even available. No, they were not tested.

Q. Okay. But you ruled them out.

A. Yes.

Q. Okay. And there was no testing of the large bottle of ready-to-feed that was used to feed Jeanine Kunkel between April

21 and April 23; correct?
A. Correct.
Q. And you ruled that out.
A. As far less likely than powdered formula.
Q. Yeah, but you ruled it out.
A. Yes.
Q. And that's the one that gets opened every single time the mother has to make a new bottle; right?
A. Mother had to take the lid off and pour it, yes.
Q. And handle it and put it in the refrigerator and take it out of the refrigerator and open the refrigerator handle door; correct?
A. Well, as a friend said to me what is -- you pour it and you put it back. Yes, she had to take it out, pour it, put the lid back on, and put it back.
Q. And there was no testing of the store-bought bottles or the hand-me-down bottles and nipples that were used to feed Jeanine Kunkel the 32-ounce ready-to-feed; right?
A. The ones that had been boiled, no.
Q. Well, her testimony was she didn't boil those. Are you familiar with that testimony?
A. No, I was not familiar that there were things she did not ever boil.
Q. Okay. But at any rate, you rule those out as a possible source; correct?

A. Relative to PIF, yes.
Q. Relative to PIF where the testing was all negative.
A. Yes.
Q. So where there isn't any testing, you rule it out. And where all the testing is negative, you rule it in.
A. You --
Q. Is that correct?
A. In looking at probability of that being the source, yes.
Q. Okay. Now, the -- our understanding which I'm sure is the same as yours is that when the -- is that the mother stored the formula that she wasn't using before it was opened under the crib in the nursery on the carpet; right?
A. We're -- we're talking about the liquid formula?
Q. All of it before it was opened.
A. Okay. Yes.
Q. Yeah. And there was no testing of the carpet; right?
A. Correct.
Q. And they had a dog at the time, little dog named Lola? Remember that?
A. I don't remember the name of the dog. I know they had a dog.
Q. And that dog had flea issues. Do you remember that?
A. I don't remember that, but I don't -- I don't think that affects my opinion.
Q. Okay. And the dog lived in the house with them, went in

and out of every room; right?
A. I don't know that detail.
Q. Okay. In any event, the dog was never tested for E. sak.
A. Correct.
Q. All right. And there was no testing of the refrigerator where the large bottle of ready-to-feed was stored or where the bottles of the reconstituted powdered infant formula were stored for that one -- that one -- the early morning hours of April 24; correct?
A. My understanding, yes.
Q. Okay. And you ruled that out as well.
A. Yes.
Q. And there was no testing of the kitchen cabinet where the infant's mother stored the bottles that were used to feed the infant. You ruled that out too; right?
A. Yes.
Q. And there was no testing of the sink in the kitchen, the sink in the kitchen, sink per se, and you ruled out the sink; right?
A. The sink area was tested and was --
Q. Not the sink, though; correct? We're going to get to what was tested. But the sink itself was not tested; right?
A. Correct.
Q. Okay. And there was no testing of the walls in the kitchen or the floor in the kitchen or the backsplash around the sink in

the kitchen; correct?
A. Correct.
Q. And you ruled those out too.
A. Yes.
Q. And there was no testing of the bottle brush, and you ruled that out too. Right?
A. If the bottle brush were positive, you wouldn't know which way the contamination went. I do agree it was not tested.
Q. Right. And so if it were on the bottle brush because somebody used the bottle brush to wash a pan that they had just cooked chicken in or spaghetti in, then you wouldn't be able to say that it didn't come from that, right, from the chicken or the pasta?
A. And I wouldn't be able to say it didn't come from the powdered infant formula.
Q. But you are telling us that you can rule it out for the bottle brush as a whole even though it wasn't tested?
A. That the bottle brush was the source? Yes.
Q. No, that the bottle brush wasn't tested -- yes, I'm sorry, and you ruled it out as a source.
A. I did.
Q. Okay. Now, there was no testing of the bottle rack where the baby bottles were dried; right?
A. Correct.
Q. And you ruled that out?

A. Correct.
Q. And there was no testing of the utensils that were used to prepare the feedings, and you ruled that out.
A. Correct. They could be contaminated from the formula more likely than the other way around.
Q. But they weren't tested, so nobody knows if there was E. sak on them or not; right?
A. And how would that change the source?
Q. I'm just asking you the question. You don't get to ask me a question back.
A. Okay. Could you repeat the question?
Q. That's okay. We'll move on.
Now, there was no testing of the home's vacuum cleaner bag contents; right?
A. I believe not, no.
Q. Right. And you ruled those out.
A. The vacuum cleaner, yes.
Q. And there was no testing of sponges and towels used to clean the kitchen. You rule those out; right?
A. As a source, yes.
Q. And there was no testing of objects that came into contact with Jeanine Kunkel: Her pacifiers, her baby blankets, her crib sheets, a rattle that was near her mouth; right? Ruled all those out.
A. Correct.

Q. There was also no testing of the baby's bathtub.
A. Correct.
Q. And you ruled that out.
A. Correct.
Q. Or the bath water itself.
A. Correct.
Q. And you ruled that out.
A. Yes.
Q. And there was no testing of the nursery environment at all; right?
A. Correct.
Q. And when the baby first came home, when Jeanine first came home, she slept in the same room, as you indicated yesterday, with her mother and father; right?
A. Yes.
Q. Okay. And there was no testing of the remainder of the home environment; right?
A. Correct.
Q. Okay. And that includes their unfinished basement that leads up to the kitchen; right? That wasn't tested either.
A. Correct.
Q. And you remember in the deposition testimony of the mother and the father that that basement was wet and damp.
A. Yes.
Q. Right? And that the little brother Kevin who was eight

years old at the time, he had a bedroom down there. That's where he slept; correct?
A. Correct.
Q. And the parents testified that they had to pull up a lot of different carpets and rugs that were down there because he'd spill and he'd have food down there and he just -- it would be too messy to keep them around; right?
A. That makes it sound very messy, but yes.
Q. Okay. Well, he's eight.
A. Exactly.
THE COURT: Miss Ghezzi, could I give everybody a stretch break now?
MS. GHEZZI: Oh, absolutely.
THE COURT: Thank you.
Thank you. Please be seated.
Q. Now, the basement had had some flooding over the years; right?
A. Correct.
Q. Okay. And there were laundry machines in the basement too, right, where the -- where -- not right where Kevin, the little brother, slept but over -- there were -- a different area was a laundry area; right?
A. Correct.
Q. Okay. And over by that area there had been some sewer back-up; right?

A. Correct.
Q. Okay. But you ruled out the basement as a possible source; correct?
A. This is an enteric organism, so yes.
Q. Well, there's nothing special about an enteric organism in terms of being able to be cross-contaminated; right?
A. You still have to get it into that mouth into the food.
Q. You do. You do. And do you know what the most common source of salmonella bacteria infection is in infants?
A. Well, there have been outbreaks from formula.
Q. Do you know what the most common is?
A. Go ahead and tell me.
Q. It's feces.
A. Yes. Well, yes, indirectly because salmonella is in feces. Cronobacter isn't in normal human feces.
Q. Indirectly in the sense that when the mother changes the diapers or changes -- or -- changes the diaper and then contaminates something --
A. But she has to have the cronobacter.
Q. No, we're talking about salmonella.
A. Yes, with salmonella, yes.
Q. Okay. Now, there was no testing of the parents or Kevin or any visitor to the home on those days when Jeanine Kunkel was home from the hospital; right?
A. Correct.

Q. And there was no testing of anyone's clothing or shoes; right?
A. Correct.
Q. And you ruled all of that out.
A. Yes.
Q. Okay. And then let's talk about the dad, Troy Kunkel. Okay. You described him as a healthy young man; right?
A. Correct.
Q. And you testified that shortly before Jeanine became ill he was diagnosed with diabetes mellitus?
A. Mellitus, yes.
Q. Mellitus, thank you. How shortly before was he diagnosed?
A. Within the month.
Q. Within the month. So some time within April you say he was diagnosed with diabetes mellitus, mellitus; correct?
A. Correct.
MS. GHEZZI: Excuse me, Your Honor.
Q. You reviewed -- excuse me. You reviewed the medical records for Troy Kunkel; right?
A. Yes.
MS. GHEZZI: And, Your Honor, for the record I'm putting up Exhibit 1005A.
THE COURT: Thank you.
Matthew, can you be of assistance? I'm not sure what the problem is, but I don't think it's -- I think it may be a

projector problem.

THE CLERK: It's a projector problem, Your Honor.

THE COURT: It was feeling neglected and has an automatic shutoff after a certain number of hours, so I'm assuming that may be what happened. We'll see. It takes a few minutes for it to warm up. So why doesn't everybody take a stretch break.

You know, members of the jury, it is -- could be a more serious technical problem, so I think I hate to take our break an hour earlier. It means we're going to have to take yet another break, but we're going to be in recess. It's 9:30. And we'll be in recess for 20 -- well, let's try 15 minutes. Then you'll get a longer break later on. But let's take a 15-minute recess until 9:45. Thank you.

(The jury exited the courtroom.)

(Recess at 9:30 a.m.)

THE COURT: Okay. Looks like we have the problem fixed. Ready to have the jury brought in?

(The jury entered the courtroom.)

THE COURT: Thank you. Please be seated.

Thanks to our crackerjack IT staff, we got the problem which we've never had before -- in the 15 years we've had a high-tech courtroom, we've had problems but not that problem. But we were able to get it fixed.

So, Miss Ghezzi, please proceed with your

cross-examination.

MS. GHEZZI: Thank you, Your Honor.

BY MS. GHEZZI:

Q. Okay, Dr. Jason. Okay. This is a hospital record from St. Luke's Hospital on April -- dated April 2, 2008; right?

A. Correct.

Q. And that was shortly before the birth of Jeanine Kunkel and her twin brother.

A. About two weeks before, yes.

Q. Okay. And this says -- and I'm going to highlight this for you -- the patient is a 24-year-old male who presents with a complaint of vomiting. The onset of the vomiting has been acute and has been occurring in a persistent pattern for days. The course has been increasing. The vomiting is characterized as bilious and has blood with pieces of pinkish flesh. The symptoms have no aggravating factors. The symptoms have no relieving factors. The symptoms have been associated with chest pain, fever, and weight loss. He's down nine pounds from yesterday. Do you see that?

A. Yes.

Q. Okay. And then if you go down to past medical history, this says that on March 18 of 2008 -- do you know what SURMC is right there?

A. No, I don't.

Q. It says he's got gastroenteritis; correct?

A. Correct.
Q. That's a GI infection; right?
A. That's back in 2008, yes.
Q. Yeah.
A. Right.
Q. March of 2008. That's when the baby was born.
A. Right, yes, uh-huh.
Q. And dehydration, hyperglycemia, known diabetes; right?
A. Yes.
Q. Okay. So his diabetes was known in March of 2008; right?
A. Correct.
Q. And he had hyperthyroidism; correct?
A. Correct.
Q. Now, does that say he was discharged on 3-19-08?
A. Yes.
Q. So was he in the hospital from 3-18 to 3-19?
A. Yes, he was there I think overnight probably for observation.
Q. Okay. And then if you look at the next past medical history, you see he's got an admission in December of 2004; right?
A. Yes.
Q. And it says diabetic ketoacidosis; right?
A. Yes.
Q. So he had diabetes at least by December of 2007.

A. Well, within -- yes, a few months earlier was diagnosed.
Q. Right.
A. Yeah.
Q. Not the same month. He wasn't diagnosed the same month as when Jeanine was born.
A. No, no, it was a few months earlier.
Q. Yeah. And there he has thyrotoxicosis; right?
A. Correct.
Q. And new -- new onset diabetes mellitus type 2; right?
A. That's what they have there. It's neither here nor there. I think they bounce around between wondering if it's type 1 or type 2, but he's insulin-dependent diabetic.
Q. Okay. And then let's look at the hospital admit for July of 2006. That's just he was in an accident and he fractured something.
A. Correct.
Q. Okay. And then you testified that he had spherocytosis; right?
A. Correct.
Q. And that is -- we call it congenital or --
A. Hereditary.
Q. Hereditary, thank you, hereditary spherocytosis, and you explained that with Mr. Rathke yesterday, but there's a problem with the red blood cells.
A. They are not shaped normally.

Q. Right. And, in fact, his was so severe that he had a splenectomy, didn't he, when he was eight years old?
A. I don't know that severe is the term. It was causing enough problems that -- what happens is that if cells aren't shaped normally the spleen can pick them up, and so that's -- he had a splenectomy.
Q. Right, he had a splenectomy, and they took out part -- a little bit of his pancreas at the time; right?
A. Yes.
Q. Okay. And that was on April -- I mean that hospital record is April 2. Okay. And then on April 25 he went back to the hospital; correct?
A. Correct.
Q. And this is the hospital, St. Luke's, which is where Jeanine was taken on the 24th; correct?
A. Correct.
Q. Okay. And so I want you to look at that highlighted portion there, and it says reason for admission. This is a 25-year-old male who has a history of insulin-dependent diabetes mellitus. He was admitted for fever with stiff neck and rule out meningitis; right?
A. Correct, and they ruled it out.
Q. I'm sorry to do this to you, but I want to -- I missed something in there, and I -- you see right in there, this is from the April 2 hospital admission, and his past medical

history -- I just want to show you this, the hyperthyroidism, you see that?
A. Yes.
Q. And he had an ablation on March 31, 2008; right?
A. Yes.
Q. And that was to take out a goiter; right?
A. To take out thyroid tissue that was -- appeared as a goiter, yes.
Q. Okay. I'm going to show you Exhibit 105B (sic), page 6. And you can't see the date very well, but -- because there's a three-hole punch there, but this is the same day, the same hospitalization, April 25, 2008; right?
A. Correct.
Q. Okay. And this talks about the patient is a 25-year-old male who presents with a complaint of headache, headache notes. He comes in with complaint of headache and states that his new daughter has meningitis. Patient states he has a fever of 103.1 the last night and fever has been up. Nausea and vomiting on and off for the last three days. See that?
A. Yes.
Q. And down for the last three days. States he has a severe headache, body aches, neck pain, and severe, sharp, stabbing pain on the left side of neck and jaw. Patient complains of severe night sweats and BGMs, bouncing up and down rapidly. What's BGMs? Do you know?

A. I don't know.
Q. Okay. And patient also complains of severe thirst. See that?
A. Yes.
Q. And, Dr. Jason, now I want to show you from the same Exhibit 1005B.
MS. GHEZZI: Okay. Thank you. Thank you. I got it, Matt. Thanks.
Q. Okay. And this is another medical record from the same hospitalization. You see this right here?
A. Yes.
Q. Admit date? Okay. April 25, 2008. And once again, it talks about patient is a pleasant 25-year-old gentleman who was admitted to the hospital with a history of fevers at 103, body aches, neck pain with sharp stabbing pain and so on. You see that?
A. Yes.
Q. His past medical problems include insulin-dependent diabetes, recent history of Graves' disease with radio ablation of a goiter. You see that?
A. Yes.
Q. And he was admitted for further evaluation. And then it says one of his set of twin daughters has proven bacterial meningitis; right?
A. Correct.

Q. And then this doctor writes assessment and plan, 25-year-old gentleman with a lot of medical problems for someone his age. See that?
A. Yes.
Q. You don't dispute his medical records, do you, Dr. Jason?
A. No, I think he has a lot of issues, but he's young, and he's dealing with them.
Q. You wouldn't describe him as a healthy person, would you, at that -- in April of 2008?
A. Well, when he's a ketoacidotic, he's not healthy, but he is in general a healthy individual.
Q. Now, you said he didn't have any GI problems; right?
A. At the time of that admission, no.
Q. At the time of that admission?
A. Well, he had no intestinal problems, no diarrhea. When you get ketoacidosis, you vomit.
Q. Okay. And I'm showing you from Exhibit 1005B page 12. And tell me if you can't read this; okay? But I'm going to put this -- can you read it? Okay. Gastrointestinal, you see that? Here's the date, April 25. Do you see that?
A. Right.
Q. Patient states it has been a long time since he has passed a regular form stool. Currently he is passing runny or soft stool. You see that?
A. Yes.

Q. Okay. We call that -- generally we call that diarrhea; right?
A. Yes.
Q. One last point with you, Dr. Jason, for me anyway is -- well, I just want to say Troy Kunkel certainly had contact with his daughter when she was home; right?
A. Limited, yes.
Q. Limited. There were many times when Megan Surber, the mom, left the home to go and visit the twin, James, in the NICU during that week that Jeanine was home; right?
A. But by her history he never fed Jeanine.
Q. Okay. I didn't ask you that.
A. Okay.
Q. Okay. He was left at home with Jeanine all the times when Megan Surber, the mom, went to the hospital to see James in the NICU; correct?
A. Yes.
Q. Okay. And it certainly had to happen that he touched the baby, had contact with the baby; right?
A. Yes.
Q. Okay. And he was in and out of the rooms where Jeanine slept. He slept in the same room that she did; right?
A. Correct.
Q. And he was the one who was in charge of preparing the family meals for Megan and for Kevin when Megan came home;

right?
A. Correct.
Q. And he was the one who was in charge of cleaning the kitchen.
A. Yes.
Q. And he was the one who was in charge of doing the laundry; right?
A. Yes.
Q. Okay. But you ruled him out as a source.
A. On his April 25 admission after observing him overnight, they found him not to have been infected with any significant organism other than a virus, and yes, I did.
Q. Actually he was placed on antibiotics which you don't get for a virus; right?
A. Yes, but they do give them anyway, and if you read the note, they thought it was probably a virus.
Q. Well --
A. And generally what happens is they go ahead and cover with antibiotics since you can't be sure.
Q. He was diagnosed with pneumonia at the time, wasn't he?
A. A probable viral pneumonia.
Q. And he was talking about coughing up and spitting up green stuff?
A. And cronobacter is not a respiratory pathogen.
Q. It's been found in sputum?

A. Of intubated people, yes.
Q. Of pneumonia patients?
A. Hospitalized patients with pneumonia.
Q. It's been -- okay. And Troy Kunkel was in the hospital on April 25, wasn't he?
A. He was admitted overnight for observation.
Q. And he was in the hospital on April 2, wasn't he?
A. Yes.
Q. Okay. And then just finally there -- the CDC did send somebody in there and the Iowa -- actually University of Iowa folks collected the samples. But the only samples that were collected were from a spot on the left side of the counter and the right side of the counter, on either side of the sink; right?
A. You mean in terms of the sink?
Q. Yes.
A. Yes.
Q. And then the other thing that was sampled was the aerator on the faucet, that little piece that comes down; and the faucet, that was tested.
A. Correct.
Q. Okay. And water samples on May 8 I think it was when they went in, May 6 or May 8?
MS. GHEZZI: May 7, Gabe? May 2, thank you.
Q. May 2, 8 days after she left the house, just the water from

that sink faucet on May 2 was tested; right?
A. Correct.
Q. Okay. And even on those samples the CDC found so much bacteria they classified it as TNTC, too numerous to count; right?
A. Correct.
Q. And the water's home supply tested positive for -- I'm going to butcher this name, so maybe you can help me out. But it's pseudomonas aeruginosa?
A. Pseudomonas is very commonly found in water, yes.
Q. So it was found in water?
A. Which is not unusual, yes.
Q. And that's a pathogen, is it?
A. No, not necessarily.
Q. Okay. You would agree with me that the family kitchen was not a sterile environment.
A. Correct.
Q. Right. And nobody's kitchen is a sterile -- has a sterile environment; right?
A. Correct.
Q. So it doesn't matter if you're a middle-income or a low-income American living in Tennessee in that study that you talked about about where they found bacteria. If somebody went to your home in Hilton Head, you wouldn't have -- you wouldn't have a sterile kitchen either, would you?

A. No, but the pattern of bacteria will vary with, for instance, what people are eating, things like that.
Q. Okay. But your kitchen's not sterile.
A. No.
Q. And I said finally before, but this is finally. You said something about the brother James, you know, well, he didn't get sick, and the only thing that was different was he wasn't fed powdered infant formula; correct?
A. That is the major difference, yes.
Q. Okay. Well, the other major difference is he didn't live in the Kunkel home the first ten days of his life, did he?
A. No, but that is where he went home to that very day that she became ill.
Q. And he didn't live there the first ten days of his life, did he?
A. No.
Q. And Troy Kunkel never visited him in the NICU, did he?
A. I don't know.
Q. Do you remember Megan saying she's the only one who went there after Jeanine got home?
A. No, I don't.
Q. Okay. And he hadn't been around the family pet or the visitors or the rest of the family; correct?
A. Well, he was certainly around the father when he came home.
Q. No, no, he wasn't actually because the father was gone for

two months to Omaha with Jeanine.
A. Well, he was in -- well, he had come in contact with his father.
Q. Not in the two months that Troy Kunkel and Megan were in Omaha with Jeanine. They didn't come back and forth; right?
A. But he did have contact with his father.
Q. When?
A. His father never saw him or held him?
Q. His father saw him when he was born, and then he went in the NICU, and then Jeanine went home two days later.
A. So he did have contact with his father.
Q. What was it? Do you know?
A. Of his father seeing him when he was born and being with him?
Q. Yeah.
A. The question is?
Q. The question is he hadn't been around the family pet, the visitors, or the rest of the family; correct?
A. Correct.
Q. Okay. And his formula in the NICU was not stored on the floor under his crib, was it?
A. I don't know.
Q. And when he got home, he was taken care of by his aunt and his grandmother because his parents went to Omaha for two months with Jeanine; correct?

A. Yes.

MS. GHEZZI: Okay. Your Honor, I pass the witness.

THE COURT: Mr. Rathke, you may do your redirect.

MR. RATHKE: Thank you, Your Honor. I'll be brief.

REDIRECT EXAMINATION

BY MR. RATHKE:

Q. Why do you rule out all of those areas that Ms. Ghezzi pointed out were not tested?

A. There has never been a single case of E. sak or C. sak infection found to be associated with any of those sources. It is an enteric bacteria. It occurs in very young infants and in people who are severely ill in the hospital. And when it occurs in severely ill people, it is not as severe as infants.

Q. Ms. Ghezzi took you through Dr. Mittal's -- and that's M-i-t-t-e -- or a-l?

A. Yeah, yes.

Q. -- article, and I've got it right here. Is there any of the points that she pointed out in the article that causes you to change your opinion?

A. No.

Q. Is it appropriate to -- is it medically appropriate to rely on the information provided by the patient or in this case the mother rather than secondhand accounts in medical documents?

A. Yes.

Q. Why is that?

A. Because medical documents can be inaccurate. They don't have firsthand knowledge, and it's a little bit like a game of telephone. You write down what you hear or what you hear somebody has heard.
Q. And that's what I asked you to do; correct?
A. Correct.
Q. But you would have done it anyways; correct?
A. Yes.
Q. In fact, one of the medical records that the defense points out says that Troy Kunkel has a set of twin daughters. Did you catch that?
A. Yes.
Q. That's not accurate either.
A. I thought that when I read it.
Q. Hardly likely that Troy Kunkel said he had a set of twin daughters; correct?
A. Correct.
MR. RATHKE: Thank you. Nothing further.
THE COURT: Any recross?
MS. GHEZZI: Nothing. No, Your Honor.
THE COURT: Okay. Now, do the jurors have any questions for Dr. Jason? Okay. You can just pass -- I'll give you a minute to write out any additional questions. And I see we've got one. We'll see if there are any more. Doesn't look like there are any more. Okay. Thank you. Oh, we have

several. Excellent.

Okay. Invite the lawyers up at sidebar to take a look at the questions. We don't need 84 lawyers. Just pick one or two.

(At sidebar off the record.)

(At sidebar on the record.)

THE COURT: This is the microphone that's activated. Does anyone have any objections to any of the three questions?

MS. GHEZZI: No, Your Honor.

MR. RATHKE: No, Your Honor.

THE COURT: Okay. Thank you.

MS. GHEZZI: You're welcome.

(The sidebar was concluded.)

THE COURT: Okay, Dr. Jason. I'm going to ask these in no particular order. Describe the amount and nature of contact you have had with J.K. and her mother.

THE WITNESS: I've never met Jeanine Kunkel. I was introduced to her mother the day I came for the trial and shook hands with her and asked how Jeanine was doing.

THE COURT: Okay. Any follow-up questions by the plaintiff?

MR. RATHKE: No, Your Honor.

THE COURT: Any by the defense?

MS. GHEZZI: No, Your Honor.

THE COURT: Okay. Second question, in FDA testing of

facilities that make PIF, how many have been found to have ES contamination since 2000?

THE WITNESS: I can't answer that because I don't have access to those records. I only have things related to these individual cases.

THE COURT: Any follow-up questions by the plaintiff?

MR. RATHKE: No, Your Honor.

THE COURT: By the defense.

MS. GHEZZI: No, Your Honor.

THE COURT: Okay. Third question, what kind of environment is required for ES to survive in various environments such as hands, dry surfaces, et cetera, then parentheses, environments outside the body, parentheses?

THE WITNESS: It generally will not survive in a viable state for terribly long. It responds pretty well to cleaning and to just everyday antiseptic use. It certainly will not divide, so even if, you know, let's say a bit of it gets on something, if it's not in something it can grow on, it's just going to sit there and not reach sizable numbers.

THE COURT: Any follow-up questions by the plaintiff?

MR. RATHKE: No, Your Honor.

THE COURT: By the defense?

MS. GHEZZI: No, Your Honor.

THE COURT: Okay. You may step down. Thank you.

Are you ready to call your next witness?

MR. RATHKE: I am. Scott Donnelly.

THE COURT: Everybody can take a stretch break till the next witness is sworn in if you like.

Would you raise your right hand, please.

SCOTT DONNELLY, PLAINTIFF'S WITNESS, SWORN

THE COURT: Please be seated in the witness box. You can adjust the chair and the microphones so you can speak directly into the microphones. And would you please tell us your full name and spell your last name, please.

THE WITNESS: My full name is Leonard Scott Donnelly. Last name is D-o-n-n-e-l-l-y.

THE COURT: Thank you.

DIRECT EXAMINATION

BY MR. RATHKE:

Q. And where do you live?

A. I live in Burlington, Vermont, at 347 South Union Street.

Q. Do you go by Leonard or Scott?

A. I prefer Scott.

Q. What's your current employment?

A. I currently am a consultant on food safety issues in the food industry. I do a number of different things. I have a contract with a large company in -- that's based in Chicago, Silliker. I do training through that company where I train food companies in sanitation. I'm HACCP certified. I teach HACCP in both the public and private setting. I'm safe quality food

certified which means I'm able to perform safe quality foods consulting and help folks become safe quality foods consult -- or safe quality food certified. I'm a safe quality food certified trainer which means I can teach the course that's involved with that particular certification program. I am involved in any number of sort of normal food industry problems where they have a particular microbiological problem and they want an outside pair of eyes to look at it and give them advice.

Recently I've been involved with doing that with companies that want to manufacture powdered infant formula and they're looking for somebody with experience in that area and able -- with a goal of producing a safe and compliant product.

That's sort of the base -- the nuts and bolts of it. I've also been involved extensively through the last year in doing what are called due diligence evaluations of food factories where the factories will be sold and then I'm asked to come in and provide a evaluation of the factory, is it capable of providing safe products or not.

So we look at sort of everything from how they make it to how they sanitize it to how they do everything related to making a safe product that the risk can be assessed for the purchase. That's pretty much my background and what I do.

Q. You mentioned some teaching and some consulting. Who hires you generally? What kind of people hire you to do those things?

A. Well, for example, I'm on the calendar for the end of

February to teach Silliker's public food microbiology course. It's a three-day course, and I'm the instructor, so we get people from the food industry. Other industries come in, and they want to have some basic knowledge about food microbiology so that they can in turn go back and either make appropriate decisions, organize their companies appropriately so they can make safe foods.

Q. Normally I wouldn't ask this, but who's your wife?

A. I'm married to what's sometimes referred to as the other Dr. Donnelly. That's usually me, but my wife, Dr. Catherine Donnelly, is a professor at the University of Vermont. And she has a area of expertise in the organism listeria which is an environmental contaminant very similar to cronobacter which we're talking about in this case. She is --

Q. And she's testifying in this case.

A. She's testifying in this case, yes, sir.

Q. Okay. How is it that you got involved in this case?

A. In this case I got involved through Cathy who --

Q. Who hired you?

A. Well, you hired me, Lommen and Abdo, yes.

Q. What did I ask you to do?

A. You asked me to take a look at what was going on inside the factory and look at all the records and try to assess the factory from my point of view and experience in manufacturing powdered infant formula and how -- basically to essentially do

an assessment related to the risk of contamination of the product for cronobacter.
Q. What factory are you talking about?
A. In this case it's Casa Grande.
Q. Cas -- and where is that located?
A. That's in Arizona.
Q. And who runs that factory?
A. Abbott.
Q. How are you paid for this work?
A. I'm paid by the hour, so it's either remote work preparing expert reports, or in this case I'm testifying. I've been deposed in this case, so that's all paid by the hour.
Q. And you're paid by the hour regardless of the outcome.
A. Correct.
Q. What percent in the average -- in the last couple years of your annual pen -- or annual income comes from being an expert in legal cases?
A. Just as a guess, I'd say 20 percent.
Q. Have you ever in your life testified in a courtroom?
A. No. This is a first for me, so I'm -- I'm finding it interesting.
Q. How would you define your expertise?
A. Well, when I -- my -- when I took early retirement from Wyeth which was --
Q. You're telling us too much. Just tell us your expertise.

We'll get to the other things later.
A. I'm an expert in food safety. I have a substantial primary expertise in how to inactivate microorganisms using both wet and dry heat. I've got publications in that area with spore formers. My Ph.D. research was funded by Abbott and involved a spore spoilage problem that they had at the company at that time.
Q. What -- tell us your education and, you know, where you went to school, what degrees you got, and when you graduated.
A. I went to school as an undergraduate at St. Olaf College, double major in biology and English, went to Iowa State University for two years, and I was a -- obtained a master's degree in microbiology from that institution. Then I went to the University of Minnesota, and I obtained my Ph.D. in food science with a specialization in food microbiology.
Q. What year did you get your Ph.D. from the University of Minnesota?
A. I think I officially graduated in '81.
Q. Give your -- in summary fashion give us your employment history since your graduation from University of Minnesota.
A. I worked for a brief period in Brookings, South Dakota, at South Dakota State for a couple years as -- in an academic position. I had a position at Clemson University for a short period of time as well where I was basically the food microbiologist there.

And then I took employment in 1983 with the company Wyeth who was building what at that time was -- it's called a Greenfield site. They're building a factory that was going to make powdered infant formula, and I was hired. I was the 12th person hired. And I was the one that was --

Q. Excuse me. And Wyeth, is it W-y-e-t-h?

A. That's correct, W-y-e-t-h. Sort of the succinct version of this is Wyeth was purchased by Pfizer which is -- purchased the nutritional business unit which is now Nestle, so it went Wyeth, Pfizer, Nestle. This is like years ago.

So I was hired to implement the microbiological systems, and as I had a Ph.D., at the Greenfield site -- it was the showpiece factory at that time in the Wyeth network, and I was always looked at as the -- as the person that was going to provide leadership and oversight for product safety issues. So I held a variety of positions.

Q. Where was the Wyeth plant located where you worked?

A. So the factory is located in Georgia, Vermont, which is about 30 miles north of Burlington.

Q. And what did that factory manufacture?

A. We made a -- strictly powdered infant nutritional products, a range of those. The product that it's most well known for as I ended my career there and which is still known today, they make Parents' Choice which is the Wal-Mart product. The brand name Wal-Mart product is Parents' Choice. That product's made

up in Georgia, Vermont.
Q. Is that powdered infant formula?
A. That's powdered infant formula.
Q. Did it make -- and you held this -- you worked at the plant for Wyeth until 2001?
A. Correct. I was based there --
Q. Okay. Thank you.
A. Yes.
Q. We're good. We need to move this along.
A. Yes.
Q. After you -- in 2001 what position did you take?
A. At that point I became involved with the corporate groups. I had a series of positions, and the factory itself was in the process of being sold, so it was sold to Paul B. Manning, and now it's Perrigo.

My position migrated to corporate, and I went through a succession of promotions, ending up being director of product safety which was my position when I left and took early retirement in 2007.
Q. And since 2007 have you been doing the consulting that you described earlier?
A. Yes. I took a very brief period off, and then it's been -- I've been very, very busy.
Q. Now, the University of Vermont is located in Burlington; correct?

A. It is.
Q. Have you had any teaching positions with the University of Vermont?
A. Over the years, particularly in the '90s, I taught the food microbiology course there as an adjunct faculty member, so that was a 3-credit course with a lab. So the -- I taught that for years. I -- I -- it was sort of a extension of what I'd done when I was at Clemson University, and I enjoyed doing it, and I did it more as -- I did it because I enjoyed doing it, liked interacting with the students.
Q. Okay. Now, tell me -- we're going to go back to your employment at Wyeth. Did it produce powdered infant formula during the entire period of time that you worked there from 1983 to 2001?
A. Yes.
Q. And what -- tell the jury what your involvement with E. sakazakii was in connection with your employment at Wyeth plant.
A. Okay. Well, the ES -- the enterobacter sakazakii issue became something that was visible to everyone in a series of conference calls in 2002 because of the outbreak of ES as associated with Portagen. And Portagen was a powdered product that Mead Johnson manufactured, and there was an absolutely clear link genetically between the organism that eventually killed -- killed the infant and they found the genetic match

with a -- in a can of Portagen powder so --
Q. So that involvement started in about 2001, 2002?
A. Correct.
Q. And so from 1983 until then, that wasn't something that was on your radar screen?
A. In the late '90s it was on the radar screen. There was enough publications out there that you were aware that there was an issue. But this -- this came home to be a significant problem for us in 2002.
Q. Okay. So now we can -- we can narrow this down by -- I'll ask you to describe your involvement with E. sak issues from 2002 to the time you left working for the plant.
A. Okay. I'll -- so in 2002 there's a number of things that occurred relative to ES out of the Portagen issue. The FDA wanted to take what are called field samples. They announced that they were going to do a field survey, so that means during their normal visit to you every year they were going to take samples.
Q. Before you get to the field survey and the history of it, just tell the jury, though, what your job at the plant was with respect to E. sak.
A. Well, okay. I was involved with essentially every -- well, I was -- I was involved with lab operations, directly involved with laboratory operations both on the chemical side, particularly on the microbiology side, so I was the one that was

responsible for how the methods were carried out, if they were carried out right, what you do with data that's out of specification, how you retest samples, things of that nature.

Q. Were there programs adopted for product and environmental testing for E. sak?

A. Well --

Q. Just yes or no.

A. Yes.

Q. And were you involved in the creation and maintenance of those programs?

A. Both creation and maintenance.

Q. Did you provide any training with respect to E. sak to your employees?

A. I provided several different kinds of training, both how to -- training in how to test, and I conducted what was called awareness training at all of the Wyeth factories globally where we explained what the ES issue was, why it was important, why it was important that the factory workers understood what the problem was so that we could make safe product that wouldn't injure our consumers.

Q. What was your involvement with sanitation and cleaning programs at the plant to address this?

A. Well, as we were -- as I was involved with implementing and assessing the data for my environmental monitoring program where we go out to the factory and we sample for specific

microorganisms including salmonella and ES or cronobacter, so I provided guidance in how to best sanitize the factory environment to eliminate those organisms, and that includes both the general factory environment and the equipment that was used to manufacture the product.

Q. Did you do any -- during that time period, did you do any training of Wyeth people outside of the plant?

A. At that point in time -- we're going to go up a little bit in the 2003 era, but yes, I provided external training for several boards of health where we wanted to show these -- show folks what we were doing both from a testing and a control point of view to provide product that we were going to import into their country and show them how -- what we were doing so that they would be assured that it was safe.

Q. Reference in this trial has already occurred to the International Formula Council or IFC. During the time that you were employed at the Wyeth plant in Vermont, did you have involvement with the IFC?

A. I was -- there was a continuing series of usually telecon, sometimes meetings. I was the -- not the leader at Wyeth in that movement, but I was always the microbiological technical resource that was representing Wyeth on the calls.

Q. Tell the jury what your understanding of IFC's function was during the -- during -- you know, beginning with 2001.

A. Well, at 2001 Wyeth at that point was -- had dropped their

membership to IFC, and with the generation or with the Portagen outbreak, IFC took on the role as an industry voice for the particular cronobacter issues that resulted.

Q. Did Wyeth rejoin?

A. Wyeth rejoined at the end of the year, yes.

Q. Who were the members of the IFC?

A. What are -- what would have been called at that point the big four: Wyeth, Nestle, Abbott, and Mead Johnson.

Q. And all four of those manufacture infant formula in the United States?

A. Yes, they do.

Q. How did the IFC generally communicate with its members?

A. In -- well, in general it was e-mails. That's basically what it was is e-mails.

Q. And when it would send e-mails, would it also distribute documents, attachments?

A. Right, there was attachments. They want -- they would have draft letters they wanted commentary on. They would have this proposal or that proposal, various things that they were wanting feedback on.

Q. And were there -- were there teleconferences?

A. Yes.

Q. How would those get set up?

A. They would be set up through e-mail. You'd sort of get a -- you know, they'd get an appointment. Everybody would

acknowledge the fact that we were available, and there would be a call-in number, and away you went.

Q. And generally speaking when the IFC would send out an e-mail, would that be sent to someone in each of the four companies?

A. Yes.

Q. And when they hold the teleconferences, someone would be on the line for each of the four countries -- companies.

A. Yes, yes.

Q. And that would include Abbott.

A. That would include Abbott.

Q. Okay. Let's pull up Exhibit 73. And what you'll see -- give the full page. Do you recognize that?

A. Yes.

Q. What does MMWR mean?

A. Morbidity and mortality weekly report.

Q. Did you say weekly report?

A. Yep, that's the W.

Q. And who issues -- who issues those MMWRs?

A. It's the CDC I believe.

Q. What's the date of that particular one?

A. April 12, 2002.

Q. And would you read the headline?

A. Enterobacter sakazakii infections associated with the use of powdered infant formula, Tennessee, 2001.

Q. Is that the Portagen outbreak that you referred to a few moments ago?
A. Yes.
Q. And -- and the company that had made the powdered infant formula involved in the Portagen incident was Mead Johnson.
A. Correct.
Q. What impact did this MMWR and the Portagen outbreak itself have on the industry and any regulators?
A. Well, the -- you know, two questions. In the industry it engendered sort of complete and utter panic, particularly on the IFC side. The regulators sort of got into a situation where they had a -- they needed to do something. They had a -- they had a death, a preventible death, from a contaminated can of infant formula, and they wanted to make sure that this didn't happen again.
Q. And when you say regulator, you're specifically referring to whom?
A. The FDA.
Q. Seventy. I'm putting before you Exhibit 70 which is an e-mail of July 2002 from the FDA to various -- to the formula companies. Let me -- before I -- just to orientate the jury, the "from" is from -- in that particular case is from the FDA; correct?
A. Yes.
Q. And then the "to," it's got a whole bunch of e-mail

addresses, but within those e-mail addresses, do you recognize representatives to IFC from all of the four manufacturers?
A. I'm not sure -- I'm not -- the -- for example, the person it went to at Wyeth was Ray Maggio, so he was compliance at the time.
Q. So he got that for Wyeth.
A. Yes.
Q. Do you see on the last line of the "to's", do you see Pamela Anderson?
A. Yes.
Q. And her -- it says Ross Nutrition. Actually who is that?
A. That's Abbott.
Q. And what does this e-mail ad -- from the FDA advise the companies of?
A. They're saying that when they visit -- and typically the FDA visits powdered infant formula factories on a yearly basis -- they said they're going to sample finished product and raw materials.
Q. And did that occur?
A. It did.
Q. Was that a concern to the industry?
A. This came out the 29th. Wyeth was the first company they visited.
Q. No. Was it a concern to the industry, though?
A. I'm answering your question. Yes, it was a concern to the

industry.
Q. Let's pull up 110. I'm showing you Exhibit 110. Do you recognize that as a copy of an e-mail from -- well, the "from" is from a Mardi Mountford, and he's got his e-mail address up there. Who is that?
A. Say again. Who is Monty or --
Q. Yeah. Who's Mardi Mountford, and who's he with?
A. That's IFC.
Q. So that's from the IFC.
A. Yep.
Q. And the e-mail was sent to you along with other -- along with that same Pam Anderson.
A. Right.
Q. And then there's copies to other people as well; correct?
A. Yes.
Q. And it references a conference call with Mike Doyle on February 21 at -- in 2003; correct?
A. Correct.
Q. And the IFC is -- who's Mike Doyle?
A. Mike Doyle's a very well-respected food microbiologist at that time at the University of Georgia.
MR. RATHKE: Call up the third paragraph. Next one.
Q. And do you see where it says, "We also want to get his," Mike Doyle's, "reaction to the statements, 'Under current FDA testing procedures, it is anticipated E. sak will eventually be

found in powdered product made by all the infant formula manufacturers. Unless this issue is addressed rationally, powder product may no longer be affordable or continue to be marketed'"? Do you see where it says that?

A. Yes.

Q. Whose statement is that? I mean --

A. That's the IFC's statement. That's -- they were coming up with a series of bullet points that they wanted to get -- to put forth, and they wanted someone credible to back up these statements.

Q. When they say will eventually be found, are they referring to the survey that was going on? Do you know?

A. I do not know that for a fact.

Q. All right.

A. They are -- I think when I read that even originally, my interpretation was that it will eventually be found in some testing -- testing venue whether it's the field survey or others.

Q. In 2003 is it true the statement that's on the memo that ES will be found in powder -- or E. sak will be found in powdered infant formula made by all companies? Is that a true statement?

A. Yes.

MR. RATHKE: Would you pull up 93.

Q. Again, an e-mail from IFC in March 2003 to the formula companies. And it's a forwarded e-mail from the FDA, and the

e-mail that's being forwarded is sent to the IFC from the FDA and says that we are sending several slides relative to FDA's field survey of powdered infant formula. Do you see that?
A. Yes.
Q. Okay.
MR. RATHKE: Go ahead and go to page 7 of the exhibit.
Q. Now, before you is page 7 which is a portion of what was sent to IFC from the FDA. Could you go through and explain to the jury what the FDA field survey results are on this chart?
A. Yes. The -- so what you have is a sample type, so finished product would be powdered infant formula.
Q. Okay. So the line that we want to look at is the first line, finished product.
A. Right. And then they were also looking at -- if you may remember in the first -- one of the first exhibits they were looking at raw materials as well, so they looked at carbohydrates; they looked at protein; they looked at fat.
Q. Well, let's just look at finished product. Explain that line.
A. So they had 22 samples tested. They tested 5. At that point they were running I think what everybody -- is still a very confusing test and test result, but anyway, they were -- 5 out of the 22 were positive. 5 out of the 22 contained E. sakazakii which is now known as cronobacter.
Q. And explain what's under the column test results.

A. That gets to my statement about the test itself. The FDA when they started the field survey did not know how many E. sak -- I keep going back, E. sak, cronobacter. It's the same organism. So I think I'll focus on cronobacter. They didn't know the numbers of cronobacter, so they developed a test that would allow them to come up with a number. It's called a multiple -- the most probable number test.

Q. Is that what MPN stands for, most probable number?

A. Right. So from a -- the easiest way to look at it is that it gives you a number, and the sensitivity of the test is .36, a fraction of a microorganism per hundred grams. So the whole thing works out to having -- or to having a testing sensitivity of 1 organism per 333 grams.

Q. That's the way it works.

A. I think that's -- that's a -- you know, I'm trying to sort of help everybody understand what can be a confusing thing, and that's the best way to look at it I think.

Q. One organism with -- in 333 grams.

A. Right. So that's what they ended up testing. They test --

Q. An organism could be just a cell.

A. Yes.

Q. And if there are less than 1, is that going to test positive, 1 per 333 grams?

A. Well, that's where it gets confusing. In this test, yes.

Q. Pardon me?

A. In this test, yes, because the sensitivity is .36 so . . .
Q. So even if it had 1 every 333, it would -- I'm not sure I understand.
A. You said what would it be per hundred grams.
Q. I'm sorry. If it had less than 1 colony of E. sak in 333 grams, would the test be negative?
A. Yes.
Q. So a quantity of PIF larger than 333 grams would test negative even though there might be a cell within it.
A. That is correct.
Q. Go to the next page, page 8. Could you explain that chart.
A. Again, so we're talking about whether -- you've got the type of product, so --
Q. Let's just talk about full-term formulas. What's meant by a full-term formula?
A. This would be a formula that is intended to be consumed by an infant that was born at a normal birth weight and had no medical issues.
Q. And what does it mean to be 4 of 14 or 28 percent?
A. That means that 4 out of the 14 samples or products they tested that met that definition were positive.
Q. And that comes to 28 percent; correct?
A. Correct.
Q. Let's go to the next page, page 9. There's some bullet points there. The first bullet point, that's something that

you've already explained; correct?
A. This is what I attempted to get into with explaining what the 0.36 MPN per hundred grams, yes.
Q. Hopefully we explained it correctly or in a manner that people can understand it. What's the second point make?
A. They tried to determine whether there was a correlation between the positives and manufacturing practices. One of the manufacturers in the United States is a dry blender, and that's a different process than Abbott, Wyeth, and Nestle were using, so they wanted to see if there was a -- the process itself was a contributor to whether it was ES positive or not.
Q. So what you're saying is companies use different processes to produce the powdered infant formula?
A. Correct.
Q. No matter what the process is, there was no correlation between that process and the results?
A. Not in this field survey, no.
Q. And then the third bullet point?
A. And then they got into a -- they wanted to know if there was a relationship between product type, particularly soy versus milk. And I'll answer your question and just end it at that. No relationship.
Q. Now, we've talked about a hundred grams and 333 grams. Can you convert that to us -- for us to ounces? How much is a hundred grams, how many ounces? Do you know offhand?

A. Well, let's look at this can of product. It's 12.8 ounces. That's 363 grams. 16 ounces is 463. I don't know. We can -- I'm not a whiz at math but . . .
Q. Would a hundred grams be about three and a half ounces?
A. Be about a quarter of a pound, 20 percent of a pound.
Q. Now, these results do not tell us how much was -- you know, how the individual companies fared; correct?
A. No, they didn't. They tried to hide that.
Q. Now, you worked for Wyeth.
A. Yes.
Q. But there's three other companies. Did -- do you know -- did you know then or do you know now what the results were per company?
A. No.
Q. Did the FDA ever release that information?
A. No.
Q. Now, did you -- as working for Wyeth, did you find out what the results were with Wyeth?
A. Yes.
Q. And did one of your samples fail?
A. Yes.
Q. Where was that batch when the FDA determined that it failed?
A. It was within our control so it was --
Q. It was on the market.

A. No, no, no, no, no. It had not reached the market yet.
Q. So it wasn't --
A. No.
Q. So what did you have to do with that batch?
A. Well, we kept it under our control, and we began an investigation, and investigation went in a number of different directions. And we tried to determine the length of time over which --
Q. So you did an investigation --
A. Yes.
Q. -- to determine how it got contaminated?
A. Yes.
Q. And whatever happened to the batch?
A. Oh, it's destroyed.
Q. Now, that -- since the batch never left Wyeth, there was no necessity for a recall; correct?
A. No.
Q. That would be a rejection.
A. That would be a rejection.
Q. If that batch had been on the market, then there would have had to have been a recall?
A. Yes.
MR. RATHKE: Seventy-four. Zoom in, too, please. Show us who's sending the letter.
Q. Okay. Is that the IFC letterhead?

A. Yes.
Q. And this is a letter on July 3, 2003, directed to someone at the FDA?
A. Yep.
Q. Christine Taylor will pop up from time to time. Who is she?
A. She was one of the officials at the FDA that was involved in this. I forget exactly what her role and her title was.
Q. But she worked for the FDA.
A. Worked for the FDA, yes.
Q. If we were to look at that letter, it would tell us that this was -- that it attaches the -- a paper to it which is on, I think, the next page, page 3.

MR. RATHKE: Is there a heading to that?

MR. PERSONS: No.

MR. RATHKE: I'm sorry. Go back to page 2.

Q. On the top on page 2 which is an attachment it says proposal for microbiological testing of powdered infant formula. Is that an area that's within your bailiwick?
A. Yes.
Q. I'm going to skip that document. We haven't got enough time. Let's go to 75.

You see on page 75 is a letter on IFC stationery addressed to a Jeffrey Kornacki. Do you see where it says that?
A. Yep.

Q. Who is Mr. Kornacki?
A. Jeff is a food industry consultant. He's somebody that I've worked with.
Q. And then there's some language on page 1 that I'd like to bring to your attention making reference to -- in the second paragraph, after also -- it was also learned. Do you see where it says that the IFC is telling Dr. Kornacki it was also learned that the agency has no intention to move away from their zero tolerance policy for this organism? By testing in this manner, FDA is implying that E. sak belongs in the same category as frank or true pathogens such as salmonella. However, based on the literature, E. sak is an opportunistic pathogen with little, if any, risk to healthy infants. If repeated, the level of testing earlier utilized by FDA would unjustifiably cause economic hardship on companies as well as consumers as a result of product rejections, recalls, and possible shortages of formula in the marketplace. Do you see where it says that?
A. Yes.
Q. The word frank, do you know what they're talking about there? Or is that a -- some kind of a typo or something?
A. They are -- yes, I know what the frank means. They're afraid that ES will be regulated in the same way that salmonella is.
Q. The sentence that starts with the word "however" appears to draw a distinction between salmonella and E. sak. Could you

define for us what the point is made in that sentence, what point the IFC is making?
A. Well, they're really not making any point at all. They're expressing several fears, and the entire statement including basically all of it is their opinion. At this particular point in time -- this is before the FAO World Health Organization 2004 risk assessment which actually addressed all of these issues. So they're stating this. There's nothing behind any of these statements, and they're largely -- they're largely expressions of concern and fear.
Q. Is there any difference in your opinion between the bacterias E. sak and salmonella?
A. There's several very different -- yes.
Q. In what respect from a regulatory perspective?
A. Well, from a regulatory perspective, you can find salmonella in a wide variety of foods and in a -- a wide variety of foods, as everybody kind of has a feeling, everything from peanuts to chicken to even occasionally vegetables, tomatoes, things that you wouldn't expect to find it.
Enterobacter sakazakii cronobacter is norm -- is associated with powdered infant formula. That's the food that it is associated with. That is the food it's associated with injuries and deaths with is powdered infant formula.
Q. The sentence that starts if repeated the level of testing earlier utilized by FDA and it goes on from there, is that a

reference to the FDA study?
A. No, it's a reference there -- it was -- the FDA started testing using the MPN method, and we described the sensitivity of the test. So it's a sensitive test. And as they're saying in this particular statement, if they test our products using that sensitivity, we think we're going to have lots of product that's going to be rejected. It's going to cost us lots of money.
Q. Do product rejections and recalls cost a lot of money?
A. Yes, they do.
MR. RATHKE: Would you go to 76.
Q. I know it's hard to read because someone has stamped confidential across it. But you'll see that the e-mail says attached are the IFC's comments on the above docket, and they're sending it to someone. Do you see where it says that?
A. Yeah.
Q. And do you know what this document is?
A. I don't remember this document, no.
Q. Okay.
MR. RATHKE: Go to page 4.
MR. PERSONS: What number was that?
MR. RATHKE: 76. Go to page 4. Go to the page before that, the page before that. Is there a page before that?
Q. Part of the document from the IFC, it says IFC would like to emphasize there's no need to establish a specific

microbiological requirement for E. sakazakii. Do you see where it says that?
A. Yes.
Q. What's that mean?
A. They didn't want to have a specification for E. sak with powdered infant formula. They didn't want to have -- they did not want to have the FDA requirements to test powdered infant formula for ES or cronobacter as a release requirement, in other words, you can't put it on the market unless you test for that organism first.
Q. So FDA has the power and authority to say you cannot release powdered infant formula to the market unless it passes certain specifications which we write; correct? They've got the right to do that.
A. There's a pathway for them to do that, yes.
Q. And F -- as far as that's concerned, FDA is opposed to that or IFC is opposed to that; correct?
A. They are.
Q. And did the FDA ever establish specific microbiological requirements for finished product for E. sakazakii?
A. The FDA specifically never promulgated or they did not write regulations to my knowledge, and I -- and that's -- so we're talking 2014. What they did do was they made it ever so clear in verbal discussions that they wanted all lots of powdered infant formula that fall under the Infant Formula Act

to be tested for ES as a release requirement. In other words, they wanted it tested and the product held, not put on the market until the results were back.

Q. So they told the companies what they ought to do, but there was not a legal requirement.

A. No.

Q. And then the companies could determine what to have for microbiological specifications?

A. Well, they're the specifications that are part of the Infant Formula Act of '80, and then they did a revision in '96 that again was never codified. So the companies were internally running some version of those specifications.

Q. Go to page 8 of this document, this exhibit. On this page the IFC tells the -- or takes the position that although proactive measures may be taken to reduce the level, frequency, and incidence of E. sakazakii in powdered infant formula, total eradication of the microorganism from powdered infant formula is not currently technically possible given the nature of food powder manufacturing. Do you see that?

A. Right. And I also see the second word is IFC believes this. So there's no data to -- there's nothing to attach to this other than their belief that this was true.

Q. But that was the belief of the IFC.

A. Well, they were fervently wanting to have anything happen except testing finished product for E. sak.

Q. Can -- is it possible to totally eradicate E. sak from powdered infant formula?
A. It's possible to manufacture product which does not contain ES, yes.
Q. And briefly how do you do that? What do you have to set up to produce powdered infant formula that doesn't have E. sak in it?
A. They're on the right track. You basically need to have what are called -- we talked a little bit about Hazard Analysis at Critical Control Points as one of my areas of expertise. Most food factories have a HACCP plan. They analyze the risk for safety relative to how they make their products, and then they try to establish points where you can control that risk.
Q. What is HACCP? And I know you'll refer to it from time to time.
A. It's called Hazard Analysis At Critical Control Points, and typ --
Q. And that's mentioned actually in the third line of this --
A. Right, right. So --
Q. So there's a HACCP plan?
A. Correct. And at this point in time the vocabulary was -- they called them prerequisite programs, but they were the programs that you would have to flesh out your HACCP plan. So, example, you have what's called an SSOP, a sanitation standard operating procedure. You're making a food product. In order to

do that safely, you need to be able to sanitize your equipment. So they sort of get there a little bit.

Q. Would it be fair to say that the essence is having a clean plant and clean equipment?

A. It is. That's what they're trying to do. What they're wanting to do is they want to -- they are in a sense a little bit ahead of the curve here, but they want to use the prerequisite control -- they want to use the prerequisite control programs to produce ES-free product, but at the same time they don't want to do what's called verification testing, that is, testing the finished product to verify that these programs actually work. Sort of go hand in glove.

Q. Now, in terms of -- how does a factory know whether or not its equipment and surroundings are clean?

A. They -- again, this is sort of a vocabulary word, but it involves what's called environmental monitoring. And this can -- you can take samples of air. You can take samples of water. In the food industry it usually involves taking either something like a Q-tip swab or more appropriately now --

Q. Well, let's just stay with generalities, but it's swabbing.

A. It's swabbing. You go out in the environment, and you swab it, and you test that swab to see if you have the microorganism you're interested in in it.

Q. And is that part of a HACCP plan, or is that kind of --

A. That's a key part of the HACCP plan.

THE COURT: Mr. Rathke, would now be an okay time to take a break?

MR. RATHKE: Certainly.

THE COURT: Okay. Members of the jury, we'll be in recess till 11:25. Thank you.

(The jury exited the courtroom.)

THE COURT: Anything we need to take up?

MR. RATHKE: No, Your Honor.

MR. REIDY: No, Your Honor.

THE COURT: Thank you.

(Recess at 11:07 a.m.)

THE COURT: Ready to have the jury brought in, Mr. Rathke?

MR. RATHKE: Yes, Your Honor.

(The jury entered the courtroom.)

THE COURT: Thank you. Please be seated.

Mr. Rathke?

MR. RATHKE: Thank you.

BY MR. RATHKE:

Q. Exhibit 82 is in front of you already, and you'll see that that's an e-mail from Rachel Spector. And is that the IFC? Is that the IFC?

A. Yes. I'm sorry.

Q. Okay. And that's an e-mail that was sent to -- did you get that one? Yeah, you got that one, and people from the different

companies got it?
A. Yes.
Q. And it says the message -- well, the subject is IFC to WHO, FAO, slash, WHO, call for data. And then the message is for your information the attached documents were sent to WHO this evening. As earlier agreed, the attached documents were also provided to those copied on the letter. Do you see where it says that?
A. Yes.
Q. Do you see where it says that?
A. I see where it says that.
Q. Go to the next page. And IFC letterhead; correct?
A. Correct.
Q. And that's being sent to a Peter Embarek of the World Health Organization in Geneva, Switzerland, and they identify him as a doctor. Do you see where it says that?
A. Yes.
Q. And it says the letter is in response to FAO and WHO. WHO is the World Health Organization.
A. Correct.
Q. What's FAO?
A. It's escaping me right this second.
Q. It appears --
A. I think it's the Food and Agricultural Organization, World Health Organization. I think that's the acronym.

Q. Okay.

MR. RATHKE: And would you turn to page 3, page 3 of the document. And the second paragraph, highlight that. First sentence of the second paragraph. You got it.

Q. Do you see where IFC is informing WHO, the World Health Organization, that since 1988 the published literature has reported that about 10 percent of the tested powdered infant formula has tested positive for E. sak? Do you see where it says that?

A. Yes.

Q. Is that a true statement?

A. I'd say yes.

Q. How would you characterize that result, that 10 percent of the tested powdered infant formula for E. sak has tested positive? What does that tell you?

A. That tells me that a good portion of the formula on the market contains ES, and that's what the Infant Formula Council is saying as well.

Q. Exhibit 113. You'll see in Exhibit 113 is an e-mail from that same person with the IFC to people of -- from the different companies. And the message is, "Attached for your information is the finalized Q and A document for Dan March to use at his preparation for the WHO workshop regarding E. sak next week, February 2-5." And you were given that as well; correct?

A. Yes.

Q. And then if you'd turn to page -- bottom of page 2, I just want to point out question 5. The question in the Q and A prepared -- oh, I should ask, who's Dan March?
A. Dan March was the director of compliance at that -- probably product safety at that point in time for Mead Johnson.
Q. Okay. And you said compliance; right?
A. Well, that was his last position.
Q. But I mean it sounded like clients, but it's compliance.
A. Compliance, right. So he was the lead person from Mead Johnson on the ES issues.
Q. And is that kind of a counterpart to your position with Wyeth?
A. Yes.
Q. Okay. So that's the question prepared by IFC, and then go to the next page for the A part. And highlight that. It says FDA's current position, that is, that the presence of E. sak is a concern, even at a very -- at the very low level of detectability, has resulted in costly product recalls for some U.S. manufacturers. It has also resulted in rejections of entire batches of raw material and of finished infant formula by all manufacturers. The U.S. industry's costs related to these recalls and rejections have already amounted to millions of dollars. Do you see where it says that?
A. Yes.
Q. And is that statement literally true? In other words,

there has been this cost?
A. Yes.
Q. 85. 85 is a document about the same date, January 30, 2004. It's an e-mail from IFC to the -- to you and representatives of the companies. Do you see that?
A. Yes, yes.
Q. And it says attached for your information are the paper and PowerPoint presentation of -- I think it's Jean-Louis Cordier.
A. Correct.
Q. Will provide to WHO at the workshop in Geneva next week, and it gives that same date. First, who's Mr. Cordier?
A. Cordier is a very well-respected technical resource that works for Nestle, so when you're talking about powdered dairy products or powdered infant nutritionals, he's considered very -- very credible in the industry.
Q. Okay. Go to the next page, the first page of the attachment. And that's what's attached; correct?
A. Correct.
Q. Now, is that kind of a practice of IFC that when somebody's going to give a presentation from one of the companies like Mr. March or Dr. Cordier that the IFC floats it to all -- you know, to all the companies so they get a chance to see an advanced copy?
A. Yes.
MR. RATHKE: And go to page 2.

MR. PERSONS: We're on page 2.
Q. At the bottom it says other heating steps are typically applied in a wet-mix process. Now, I know we're jumping in kind of in the middle of this and this hasn't been thoroughly explained, but real quick, what's the killing step that occurs when powdered infant formula is made?
A. In the process that my company used and the process that Abbott used, they have a -- they make a liquid mix, and they put it through a pasteurizer, essentially a killing step where the liquid is heated to a temperature where it will kill microorganisms.
Q. And it's in liquid at that point, of course.
A. It's liquid at that point.
Q. And it will kill all organisms.
A. It won't kill every microorganism, but it will kill the pathogenic microorganism.
Q. It will kill all the E. sak for sure.
A. It will kill all the E. sak, all the salmonella. They will be killed.
Q. All right. That's the context. And then he says other heating steps are typically applied in the wet mix process, and he identifies numbers of them, a preheating of the liquid formula in particular after an intermediate storage and, two, the actual spray drying. And we'll go to the top of the next page to finish that paragraph. And then in describing those

two, he says although they may have some killing effect in particular, these two steps are performed for technological reasons and are not considered as critical control points. Do you see where it says that?

A. Yes.

Q. What's he mean?

A. He means that the actual -- well, he's talking about two things. One, he's talking about heating up the liquid prior to introducing it to the dryer and saying that there might be some kill there, but it's not something that can be quantified. There's not a way of providing a read-out that says that all of the product got that temperature. And then once the product's injected into the dryer, you're exposing it to dry heat and high temperatures, and there's potentially some amount of kill there, but again, it's not sufficient to be used as a critical control point where you can control, reduce, or eliminate the pathogen. It won't do that. There will be microorganisms that will work their way around both of these treatments.

Q. So the heating processes, these two heating processes, are simply part of the process of --

A. Correct.

Q. -- of manufacturing.

A. Correct. They're part of the manufacturing process.

Q. And is Dr. Cordier correct in his description?

A. Yes.

Q. Now, you read the deposition of Sharon Bottock who's quality control or has some similar title at Casa Grande for Abbott.
A. Yes.
Q. And do you recall that Ms. Bottock identified the spray drying process as a killing point?
A. Yes.
Q. Is that accurate?
A. No.
Q. Why not?
A. The -- there's a little bit of background here. This is dry heat, not wet heat. So dry heat is not nearly as efficient in killing microorganism. If anybody's ever had a steam burn, you're aware of the fact that steam is like much more powerful than just dry air. You can stick your hand into an oven in the kitchen, but you don't want to stick it into a stream of hot steam, sort of the same thing.
Q. You're talking about in the dryer.
A. In the dryer. It's hot air. And the other way to look at this is the scientific term is latent heat evaporation. You stick liquid in there with the hot air, and as it evaporates, you use a certain amount of heat energy to evaporate the water off which keeps the powder particles cool, so the powder ends up looking more like my glass here than the color of this little speaker cover. If there was truly heat that would inactivate

microorganisms, the powder would be black, not white.
Q. Page 5. Page 5, Dr. Cordier says the processing environment is not sterile. That's, of course, a true statement. And then he goes on to say that enterobacteriaceae has been traditionally used as indicators to assess for deviations in the high hygiene area. Okay. Let's talk about a couple terms there. What's he mean by an indicator?
A. Well, the food and dairy industry have for years before there was technological means to directly test for an organism used microorganisms that were easy to grow and count in a relatively unsophisticated laboratory as a way to provide an indicator of whether a pathogen is tested -- is present or not.
A good everyday example is testing drinking water or when you go to the beach they tell you, oh, we tested the water and it's got coliforms in it so you can't swim there. Okay. Well, the coliforms are an indication that there might be pathogens like E. coli or salmonella that might make you sick, so that's the concept of an indicator.
Q. It indicates.
A. It indicates and --
Q. At least it's supposed to.
A. It's supposed to.
Q. He also -- there's a term in there, high hygiene area. What's that mean?
A. In factories that are making sensitive foods -- and Abbott

Casa Grande's making the sole source of -- ready-to-eat sole source of nutrition for an infant, so in certain areas where the product is exposed to the factory environment, you have to be very careful about whether you contaminate the product as it's in those areas. You don't want a factory contaminant to go into that ready-to-eat food for the infant.

Q. So they zone the factory?

A. They zone the factory. Some areas are high hygiene. Some are low. Warehouse would be considered a dirty area. The dryer tower, the packaging areas would be high hygiene areas.

Q. And is his observation correct that enterobacteriaceae or EB has had at least at that point been traditionally used as an indicator to find deviations in the high hygiene area or what's sometimes called the red zone? I mean, is that a factual statement?

A. In Dr. Cordier's Nestle world, that statement would be true. Nestle was known for using EB as an indicator of whether their process areas were microbiologically clean or not.

Q. Well, I don't think he's saying it's always used, but it was used.

A. It was used, yes.

Q. And in 2008 at Casa Grande --

A. They were --

Q. -- what was Abbott's practice?

A. Abbott was using // as a way to evaluate their high hygiene

areas.

Q. Is EB -- when you test for EB, is that a reliable indicator for the presence of E. sak?

A. No.

Q. Why not?

A. It's kind of a -- when you look at the definition of enterobacteriaceae, it's kind of a seemingly intuitive thing to do. It's like, okay, you've got this family of microorganisms. There's salmonella in there. There's E. sak. There's E. coli. There's a whole host of things. And if we just look for EB which is pretty easy to do, we can give us -- we can provide some indication of whether the pathogen is present or not.

And it's -- the problem is that both -- particular ES has a much different competitive profile in a dry powder factory than a lot of other EBs do. So there really isn't any correlation between EB in the factory environment or EB in finished product.

And that was actually one of the -- one of the areas that was addressed in the 2006 risk assessment and was -- the connection between using EB as a indicator for pathogens was conclusively put to rest as not being correct.

Q. No. I mean now, now, at the present time, or has that all been changed because of subsequent knowledge?
A. It depends. The means are there to directly test for the pathogen, and that's what most people do.
Q. Okay. Is there any doubt in the scientific community that EB is not a reliable indicator for E. sak?
A. No, it's settled science.
Q. He -- Dr. Cordier also says on page 6 that under such conditions the control over the presence of water, and then in paren, infiltrations, condensations, cleaning water, et cetera, becomes even more important and critical. While the presence of water does not necessarily -- has not necessarily an immediate impact on the presence of salmonella, it has an immediate effect on the increase of enterobacteriaceae. Such increases can only be prevented by thoroughly reviewing all process steps, procedures, running of services such as air, by strengthening the dry cleaning procedures, et cetera, to maintain populations consistently at the low levels indicated above. Do you see where it says that?
A. Yes.
Q. Is Dr. Cordier correct when he says that?
A. He's -- he's got one particular thing completely right, and that is in a dry powder factory -- in fact, I'll give everybody sort of the key piece of information is you need to follow the water. So water in a dry powder factory is like pouring

gasoline on a fire. However, that's what you need to control. Whether there's EB or not really doesn't reflect. You need to control the water. If you control the water --

Q. What happens when water meets the product in the dry area?

A. You got water, you got food. You can potentially get something to grow. Microorganisms are very small. They're about one micron in size. You can't see them with the naked eye. Factories are factories. They got cement floors. They got tile floors. They got cracks. They got crevices. It's very easy to have what's called a microbiological niche. You get a little bit of water, you get a little bit of food, and you can have the organism growing.

Q. Then also on page 6, Dr. Cordier says in the last sentence there the sample size analyzed will normally depend on the type of infant formula, that is, products for premature or newborn babies versus products for older infants. Do you see where it says that?

A. Uh-huh.

Q. What's -- is that -- is that a true statement?

A. Yes.

Q. And could you explain it to the jury.

A. Well, there's -- the whole FAO WHO process was aligned or set up in a way that it was trying to attach a risk to -- to the possibility of ES infections from particular products. And some products are more -- they're going to be consumed by infants

which are at higher risk such as infants that are less than six weeks of age or they're of low birth weight or they have other issues and n --

Q. Would an example -- would an example of a product like that be --

A. NeoSure.

Q. -- Abbott NeoSure?

A. Right. So the --

Q. Okay. So what is Dr. Cordier saying what you gotta do if you're manufacturing a product like NeoSure?

A. He says a sample size for the higher risk products should be larger.

Q. The -- larger than for more mainstream formula?

A. Correct.

Q. And when he says sample size, what's he -- what's that making a reference to?

A. It's not within the context of that statement. But I believe he's referring to the number of samples. Factory contaminants like salmonella and E. sak are heterogeneously distributed. That is, they kind of are -- they happen. They're random. But they're not homogeneous. So for a heterogeneous contaminant, you need lots of samples. For a homogeneous contaminant, you can take a relatively few number of samples and get the same result.

Q. So did you see anything in this case in the deposition of

Sharon Bottock or anyplace else that Abbott used any type of enhanced testing when it was making its NeoSure product?
A. No.
Q. Exhibit 90. Exhibit 90 is a paper entitled Powdered Infant Formula Industry Practices and Standards in the United States of America. And it's directed to the WHO workshop, the one we've been talking all along about in February 2004, and it's authored by Daniel March. Do you see where it says that?
A. Yes, yes.
Q. And we don't need to go through the whole paper, but I will hand you the paper, and you'll see that in the paper Dr. March has headings entitled the Manufacture of Powdered Infant Formula on page 2. He's got another chapter or heading In-Process Control Program/GMP, and that's on page 3. Do you see where that is?
A. Yes.
Q. What's GMP mean by the --
A. Good manufacturing practices.
Q. So Dr. -- is it Dr. March or --
A. No, it's --
Q. Okay. Mr. March. Mr. March sets out some standards. Now, you've reviewed this paper before, have you not?
A. Yes.
Q. Do these papers -- does this paper and Dr. Cordier's paper that we just went through, do they provide appropriate industry

standards for that time period in connection with the manufacture and control of -- manufacture of powdered infant formula and control of E. sak?

A. Yes, yes, they provide a adequate description of industry practices.

Q. And were those industry standards and practices generally the same in 2008?

A. Yes.

Q. And when you reviewed this case, did you have those standards and practices in mind?

A. Yes, I did.

Q. 101. 101 is an e-mail from the IFC to you and various other people in the industry including Abbott, and it says for your reference the attached letter providing IFC comments relating to this code -- well, that's what's attached. Do you see where it says that and there you'll see a letter to Dr. Farber? Do you know -- who's Dr. Farber?

A. He's -- as you can see, at that point he was director of Bureau of Microbial Hazards in Canada. So he was the one that was heading up the practices effort for CODEX.

Q. On page 3 you'll see where the IFC in its letter to Dr. Farber makes the point that the safety of foods for infants and children is not the sole responsibility of manufacturers. Thus, emphasis should be placed on education for consumers and healthcare professionals. And then it indicates that he's

enclosing a brochure developed by the IFC to address preparation and handling of powdered infant formula. Do you see where it says that?

A. Yes.

Q. What -- and -- what is your reaction to the IFC taking that position?

A. The IFC was pretty early on as a industry voice trying to deflect blame and responsibility and --

MR. REIDY: Your Honor, if I may, I would interpose an objection to the witness testifying to the intention of the IFC.

THE COURT: I think you can give a -- well, why don't you lay a better foundation for it. I'm going to sustain the objection.

MR. RATHKE: I'm going to withdraw the question.

BY MR. RATHKE:

Q. And actually I'm going to ask the same question, but listen to it. What is your reaction? I wanted your reaction, not necessarily the IFC's position. Tell us what your reaction is.

A. I didn't agree with it.

Q. And why not?

A. To my point of knowledge working within a company and working to control ES and make safe products, it's possible to do so, and it's possible to do so so that -- I mean, this is blaming the consumer and that's -- you make a safe product, and you put it on the market. You don't make a product that's not

safe and expect a consumer to do something else that's going to make it safer. That's -- ES in this particular case is preventible, and this kind of attitude suggests that it's not.

Q. 104, please. 104 is a e-mail from -- well, IFC e-mail to its contacts including board of directors. And it says that on January 17 IFC people had a very productive meeting with Dr. Anna Bowen and some others with CDC and somebody from the FDA to discuss E. sak issues. Do you know who Dr. Anna Bowen is?

A. Yes.

Q. And who's she?

A. She was the one that was on the CDC side of things keeping track of ES outbreaks and was trying to push the FDA along for stronger enforcement.

MR. RATHKE: And could you highlight that part about . . .

Q. Do you see where it says of particular interest?

A. Yes, yes.

Q. It says of particular interest, Dr. Bowen -- or Drs. Bowen and somebody else disagreed with IFC's citation that, quote, FDA is not aware of E. sak infections among healthy, full-term babies in home settings. Do you see where it says that?

A. Yes.

Q. They, referring to Dr. Bowen and her colleague, noted that there had been a number of cases that had occurred in the home

with healthy infants. Do you see where it says that?
A. Yes.
Q. And then it goes on to say we acknowledge there have been some mention of these cases at a recent IFC meeting with FDA. Do you see where it says that?
A. Yes.
Q. Do you agree with Dr. Anna Bowen's observation about healthy, full-term babies?
A. I agree with -- I have no data to back that up. In my memory -- I have a memory of the meeting, and I have memory of her providing some details about infections related to term infants and older, healthier infants, and I just have to take her at her word.
MR. RATHKE: And then the next, we noted, we noted. Second sentence. You got the right paragraph.
Q. Do you see where the memo goes to say we, meaning the IFC people, noted there are manufacturing and financial aspects surrounding the production and consumption of powdered infant formula around the world and expressed potential difficulty in trying to reduce PFI (sic) use? Do you see where it says that?
A. Yes.
Q. Then it goes on to say that one of the CDC doctors expressed a strong need to make PIF sterile which would eliminate almost all negative aspects of PIF use. He added it is unacceptable. There is no way to make PIF sterile, could not

believe that this could not be accomplished and suggested industry consider providing funding or incentives to universities in an effort to produce sterile powdered infant formula. Do you see where it says that?

A. Yes.

Q. Can it be made sterile?

A. In my -- I was -- in the last year of my time with Wyeth, we had formed a team to do just exactly that. The goal was to provide -- to produce sterile PIF.

Q. Do you know what the financial considerations that the IFC makes to the CDC? Do you know what they're referring to?

A. Well, they're -- they're --

MR. REIDY: Your Honor, I would impose an objection again unless he had some role in this letter or some understanding of what the IFC was thinking.

THE COURT: He can answer if he knows.

A. The IFC is always concerned about communicating that if the FDA or regulations came out that they didn't agree with it would likely drive up the cost of product, and that's what -- that's what they're saying here as well. They're concerned about the money.

Q. And then to 107. 107 is another e-mail from IFC to industry people, and it indicates that on April 19 I, meaning presumably Rachel Spector, met with Dr. Anna Bowen and Dr. Chris Braden, CDC, for two hours to present the presentation -- or

discuss the presentation Bugs and Babies -- Bugs and Baby Bottles, E. sak Disease in Powdered Infant Formula, given by Dr. Bowen at a meeting.

MR. RATHKE: Could you call out -- I guess it's on page 2.

Q. And they're kind of summarizing the meeting. Dr. Braden, one of the CDC doctors, acknowledged the work the industry has done addressing this issue but clearly does not believe the issue is only a function of proper preparation and handling of the reconstituted product -- or formula. Do you see where it says that?

A. Yes.

Q. Do you agree with Dr. Braden?

A. Yes.

Q. Brandon?

A. Yes.

Q. And then further on, page 3. Do you see where it says the reason why the CDC is focusing on E. sakazakii infection?

A. Yes.

Q. Even though it is so rare is because of the high mortality rate and the belief that this infection is preventible. Do you see where it says that?

A. Yes.

Q. Do you believe it's preventible?

A. Absolutely.

Q. So how can you -- how can you make E. sak -- or powdered infant formula E. sak-free?
A. There's -- pretty much as you led in with Dr. Cordier and Dan March's paper, there's some relatively simple industry standard methods for doing that. One is you have your factory hygienically zoned in an appropriate manner. You have a sanitation program that's effective and is verified to be effective, so that's the sanitation pre -- microbiologically clean factor. You have an environmental monitoring program that's effective and used to verify the sanitation program and whether your manufacturing environment is suitable for the manufacture of these high-risk products. I think those are the three big reasons, ways to do it.
Q. Exhibit 109. You see that Exhibit 109 is an e-mail from IFC to -- this e-mail is to Dan March, but it forwards an e-mail from IFC to representatives of the industry including Russell Merritt of Abbott. And it's entitled the six-month global strategy plan -- do you see where it says that? -- and dated August 2005.
A. Yes.
Q. Okay. Let's go to page 2 where the paper discusses possible negative outcomes. And listed there is required inappropriate warning statements on powdered and possibly liquid infant formula products. That's one of the possible negative outcomes. Do you see where it says that?

A. Yes.
Q. Restrictive legislation in the United States and globally further impacting the labeling, promotion, sampling, and availability of infant formula. That's a negative for the IFC; correct?
A. Correct.
Q. A shift and restriction in availability whereby infant formula becomes a commodity or prescription-only product. That's a negative thing there. Were these concerns of the IFC?
A. Yes.
Q. And then to page 4. And I think we'll find on page 4, it starts out at the bottom of that paragraph, it says examples of negative action.
MR. RATHKE: And then highlight -- you're right there.
Q. Examples of negative action and then the bullet points. There's a few bullet points listed there. But I'm going to center on the last one. A possible negative action would be the WHO resolution passed by the World Health Assembly encourages manufacturers to inform healthcare professionals, parents, and other caregivers through an explicit warning on packaging that powdered infant formula may contain pathogenic microorganisms and must be prepared and used properly. Do you see where it says that?
A. Yes.
Q. Was that a concern of the IFC?

A. Very much so.
Q. Did the IFC regard that type of requirement as a negative action?
A. Yes.
Q. Okay. Thank you. I'm --
MR. RATHKE: Just to inform the Court, I'm going to a different subject, so shall I just proceed? I just want you to know, if you wanted to take a break or a stretch break.
THE COURT: Oh, okay. I didn't know what you were talking about. I'm not clairvoyant. Yeah, we can take a stretch break.
Thank you. Please be seated.
BY MR. RATHKE:
Q. What Abbott records did you review in connection with your engagement to analyze their process?
A. I reviewed the batch records relative to this product and many other records relating to their procedures for testing it and a whole host of documents related to the manufacture.
Q. And that would include the environmental testing results?
A. Yes.
Q. Now, after Jeanine's illness was reported to Abbott, there was an investigation. Did you review those records?
A. Yes, I did.
Q. And did you review any policies and procedures that Abbott provided describing their policies at that -- during that time

period?
A. Relative to -- be more specific there.
Q. Relative to manufacture and testing.
A. Oh, yes, yes, of course, went through the whole --
Q. And HACCP and cleaning and so forth?
A. Yes.
Q. And did you also review depositions of various Abbott employees, personnel that were deposed?
A. Yes.
Q. Did you reach any opinions to a reasonable degree of certainty in your field regarding the manufacturing and testing process?
A. Yes, I did.
Q. Could you tell those in summary fashion at first.
A. Well, the manufacturing and testing was defective, negligent and defective.
Q. Did it conform to the standards of the powdered infant -- industry in respect to manufacture and testing?
A. No.
Q. What do the batch records tell us regarding this particular batch that's the subject batch in this case as to time and process of production, and I think that's something you want to refer to your report on?
A. Right. I -- that's the easiest way to do it. The product was dried on January 8 of 20 -- of 2008, and it was packaged a

couple days later, and it ended some time on 1-11. So it began drying on 1-8 and then finished packaging on 1-11.

Q. Were you able to determine how big this lot was? And why don't we identify the number of the lot. Do you have that in front of you?

A. No, I don't.

Q. Okay. Well, go ahead. How big was this lot?

A. The lot was -- so I guess it depends -- there was essentially two lots. One piece was shipped to Canada. The other piece was marketed in the United States. Each of them had about -- one had a little bit more than 13,000 6-packs cases. The other one had about 12,000. So at the end of the day, you've got 2 lots of product that are roughly 70,000 cans of 12.8 ounces each.

Q. Is there anything in particular about the significance of the size of this lot, particularly in relation to what's typically manufactured?

A. The two lots com -- well, any lot when you got 70,000 cans is a large lot. If you combine them as a total with 140,000 cans, that's a very, very, very large lot of product. It makes it a production entity that becomes difficult to do a whole number of things that you might need to do with it. It's going to be difficult to reject simply because it's large and the monetary value is so large, so there's a -- working in one of these companies, I can tell you there's a process you go through

that does include that evaluation.

And the other piece is once it's on the market that's a lot of product out there, so it's tough to get it back if you want to get it back. So in a way it's too big to fail.

Q. How should the equipment and factory areas after drying be kept clean? How do you clean them?

A. After the drying in the dry areas, there's generally a physical cleaning either through sweeping or for vacuuming. We're talking about the factory areas now, not the equipment. And for modern factories, the factory environment itself is also sanitized. In other words, there's a sanitizer used. There's a number of commercially available sanitizers. The food industry in general uses what are called quaternary ammonium compounds for these. These are -- they're called quats, and they're a wide -- they kill all kinds of different bacteria, and they're widely used in the factory environment for that purpose. So that is how you would maintain microbiological control in your factory environment itself. You would sanitize it.

Q. You know, I should have asked this question before, so I'll ask it now. Could you give us some kind of an overview as to how Abbott produced their powdered infant formula at the Casa Grande site? And I think we're going to pull up a slide to help do that. Is that the slide that helps do it?

A. That's the slide that helps do it.

Q. Okay. Let's do that then.

A. I actually modified this from a slide that I'd produced for Wyeth. The processes are very similar. And as I -- as I was intimating earlier, in dry factories -- this is a dry powder factory. Water's the enemy. So you've got typically what's called the wet side and the dry side.

The wet side is everything that's where it's liquid. And usually the wet side ends right after it goes through the evaporator. In this case -- excuse me, the pasteurizer. In this case it's going to go through the evaporator and probably dryer heat -- dryer preheater and go up to the dryer.

Q. Now, tell us about this dryer.

A. Right. So the --

Q. It turns it from a wet mixture to a dry mixture.

A. So the -- these are little boxes, and they kind of -- they're gross oversimplification as to what's going on here. But the dryer piece of it is they're taking liquid mix, and it's a large building. I think the -- it's like 16 levels, eight or nine stories. It's a gigantic -- it's a gigantic stainless steel tube, so they're shooting in the liquid on the top, and as it's falling to the bottom, it's drying into powder. And it's a -- it's a big piece of equipment. And it's -- there's lots of stuff going on. It's not just that. You've got an exhaust stack at the top that's pumping out hot air. You've got cyclones that are attached that are knocking the powder out of the hot air on the bottom.

[illegible] --

Q. Let me stop you there. How does then that dryer work? It starts at the bottom and goes -- how does it get dry? How does it dry the powder?

A. It's like drying clothes. It's evaporation. You put it -- you put the liquid in at the top, and as it falls -- it's misted in there, and as it falls, it dries. Kind of like overspray. If you're painting a car or something or a fence, you get the overspray as the particles dry and stick to things.

[illegible].

[redacted]

In a more typical situation in 2014 you'd have a dryer that did the drying and the agglomerating piece all at once, so you don't have these two pieces of equipment. You have one piece of equipment.

So any time you have a extra process on this red side of the process which is the dry side, you introduce the chance of the product being contaminated either by worker intervention or by unclean equipment. There's all kinds of different things that can happen on the dry side, so it's just one more big piece

to what's going on.
Q. Some people have described this process and this equipment as state of the art. Was this state of the art in 2008?
A. I -- from a how you make the powder point of view, no, it's not state of the art.
Q. What part of it is not state of the art in 2008?
A. I have -- I've got -- I have personal experience because Wyeth when I had -- [illegible] And the new dryers we put in in Mexico and in Singapore in -- when was it? -- 2010, the Greenfield site that's now Nestle in China all had -- had dryers where this occurred.
MR. REIDY: Your Honor, I object to 2010 changes as an expression of what the state of the art was in 2008.
THE COURT: Sustained. The jury's advised to disregard the last answer of the witness.
Q. Yeah. We just want to know what was available in 2008.
A. Okay. Well, this is 1994 technology, so 2008 this technol -- this technology had been removed from Wyeth factories and was not something that was, from my considerable experience, something that was done in the industry in general. [illegible]

[redacted] All kinds of things can happen.

And on the packaging side, this is where the powder's actually being put in the can, so, of course, it's completely exposed to the factory environment because you're putting powder into a can and then putting not the top on it but the lid on it. And that's happening -- there's many things that can happen in the packaging environment. They can have jams. They can have all kinds of things.

One unfortunate practice I've seen many times is topping off low-weight cans where you'll actually have a human being that will be used to take cans that are low weight and put a little spoon of powder in it to get it up to weight. These kind of things happen in powdered infant formula factories and

all contribute to the reasons why this dry side is a area that is of concern for ES.

The other piece that contributes to this -- well . . .

Q. How -- how do you control bacterial problems in the dry side of the process?

A. Okay. You've got to do -- control particularly of ES in these areas is -- is severalfold. The key thing is you need to control the use of water, and then when you do use water to clean, it has to be followed with a sanitizer; okay? And I'll repeat that. It has to be followed with a sanitizer. Otherwise what happens is enterobacter sakazakii, it's a unique little thing that it has in the world that makes it different from other bacteria is it resists drying. It's called dry stress resistant, but it just resists drying better than other bacteria.

So if you wet clean something, you don't sanitize, you're going to provide a competitive opportunity for this organism to grow and to establish a presence.

And I have personal experience with the larger pieces of equipment that are cleaned in place such as the agglomerator in particular and the dryer. If these larger pieces of equipment are not treated with a sanitizer as a final rinse, they will produce product that's ES positive from time to time. It's something that is needed to control ES as the question was phrased on the dry side. If you have to take something apart to

clean it, that gets to be a different deal. That you really have to be careful about. It's gotta be done in a very controlled manner. And again, you need a sanitizer at the end of the process for pieces of equipment they have to take apart.

And so all of these things that connect up, ///, //, ////////////////////, a lot of this equipment, it's big. You can't really take it somewhere. You can't put it in a dishwasher somewhere. If it can't be cleaned in place, you've gotta take it apart and do it right there in the factory. So that's what happens as well.

Q. Can you tell us a little more about this sanitizer? You know, what is it, what does it do?

A. Well, there's -- the sanitizer for the clean in place is -- there's a number of different brands, but I talked about quaternary ammonium sanitizer for the general factory environment. These things are called peroxyacetic acids, hydrogen peroxide. It's hydrogen peroxide is what it is. So it's an oxidizing agent that basically chews up the bacteria. And it's no rinse because the hydrogen peroxide just basically goes away as it's sitting in the -- it's not something that's going to be transferred to the product, so you don't have to rinse it like you would with a chlorine sanitizer.

Q. Was this process of using the sanitary rinse that you've been describing, was that industry standard in 2008?

A. It was. And I work with so many industries. In the powdered infant formula industry, yes. And almost --
Q. And I meant -- I should say in the powdered infant formula industry.
A. Yes, yes.
Q. And is that described by March and Cordier in the papers that we've looked at?
A. They talk about using appropriate sanitation procedures. They don't get as detailed as I do, but that's what they talk -- you need to sanitize the equipment.
Q. And did Abbott depart from this method that you've described as optimum and industry standard?
A. Well, from the description their expert gave for their CIP process, // and there is no sanitizing rinse.
Q. There was no sanit --
A. No sanitizing rinse.
Q. Let's move to environmental testing, in particularly the environmental testing that occurs in the dry side. Why does a company want to test the factory environment and equipment for bacteria?
A. Okay. This is -- this is something I'm really passionate about because I end up working with folks both that have problems and try to do things. But the way it works is if you don't have the pathogen in your raw materials and it's not

present in your factory environment, intuitively you can't contaminate product. So in this case with this process, you're going to provide a inactivation step that will keep -- take the raw material piece out of it. That's -- you're going to inactivate any cronobacter that were in the raw materials.

Q. That's by pasteurizing.

A. That's by pasteurizing. Dry side, however, is a different story. And in order to control both salmonella and cronobacter, cronobacter in particular, these are factory contaminants. They contaminate the product as it's going through this process on the dry side of the factory. The only way that you know if you're in control of your factory is to test the factory environment directly for the organism, for cronobacter in this case.

And that's stated in the industry practice, in the 2000 CODEX. They want folks to have an environmental sampling plan. That goes back to the early stuff from Cordier and March where they wanted environmental sampling plans as well. You need to have information on whether the organism is in your factory and it tells you if your sanitation program is working; okay? If you're out there sanitizing and you've got organisms, okay, well, you need to do something different. You need to control your factory environment. You need to sanitize it properly, so that's the purpose of the environmental monitoring program.

Q. What was Abbott -- when they took environmental samplings, what were they testing for?

A. They were testing for [redacted] So the technologically appropriate thing would be to directly test for the pathogen instead of an indicator. They certainly had the capability. The use of [redacted] will drastically -- really won't give you very much good information about your factory environment relative to contamination with cronobacter. If you do find it with the methods they were using which are not very sensitive, if you do find it, it tells you that the environment is thoroughly contaminated, not just a little bit, but like if you look hard with the right methodology, you're likely to find it in many, many, many more samples throughout the factory.

Q. If you use [redacted] sample is negative, can you miss E. sak?

A. Yes.

Q. What was Abbott doing if it found [redacted]?

A. They had a -- they had a program where they -- it was a written program -- on whatever day they came out and they sampled whatever place they were sampling. [redacted]

[redacted] It was more than they wanted to see in their program.

Q. Incidentally, is this area of how to test, what to look for, you know, the actual testing procedure, is that -- is that an area in which your wife, Catherine Donnelly, would have more experience or expertise?

A. She's got expertise on that.

Q. Okay.

A. On the methodology.

Q. All right. So let's -- so we'll cover that with her, and we'll just cover some more broad points with you.

THE COURT: Yeah, but before we do that, Mr. Rathke, I'm going to give the jury the last break for the day.

So, members of the jury, it's about 12:32. We'll be in recess until 5 minutes to 1. Thank you.

(The jury exited the courtroom.)

THE COURT: Anything we need to take up?

MR. RATHKE: No, Your Honor.

MR. REIDY: No thank you.

(Recess at 12:32 p.m.)

THE COURT: Bring the jury in, please.

(The jury entered the courtroom.)

THE COURT: Thank you. Please be seated.

You may continue, Mr. Rathke.

MR. RATHKE: Thank you, Your Honor.

BY MR. RATHKE:

Q. Dr. Donnelly, did you review Abbott records to determine the method that they used to collect the environmental samples?

A. Yes, I did.

Q. And what was that method?

[illegible] --

Q. Let's talk about what they did first.

A. Okay.

Q. Have you described it completely?

[illegible].

Q. Does that make a difference?

A. It makes a huge difference, and the reference I'm using is the FDA method. [illegible].

The other --

Q. Why is that? What's the diff -- what happens at one temperature but not the other?

[redacted].

Q. The idea of the testing, once you've collected the sample, is to grow the bacteria.

A. Correct.

Q. And the difference in the methodology affects whether the bacteria will grow.

A. It does.

Q. Now, Abbott doesn't want to find bacteria in its factory;

correct? I mean, no infant manufacturer wants to find bacteria.

MR. REIDY: Your Honor, I object to leading. I object to leading, Your Honor.

THE COURT: Sustained.

BY MR. RATHKE:

Q. And then before you went off on another topic, we were talking about the collection -- you described the way that they collected it. Is there anything wrong with the manner they collected it from the surface itself?

The typical thing that's done with the sponge swabs is you try to -- you try to swab as large a area as you need. If you're going after a drain, you take the drain apart, and you get in there, and you go after all the different parts of the drain and get down to where the lip is between the pipe and the drain.

And what you do then is you are interested in finding out if you've got one organism and if --

If you were to use a preenrichment technique which is -- again, the industry standard is to take the sponge and put it in a nonselective medium such as lactose

broth. You let it go for 24 hours plus or minus 2, and then you can link it to whatever detection system you have.

[redacted].

Q. What does the term preoptional -- preoperational inspection mean?

A. Preop inspection is an evaluation of the manufacturing environment prior to manufacturing product. And this can be visual. It can be microbiological. You can take swabs of your factory environment, test them, see what the results are prior to manufacturing in that environment.

Q. What procedure starts this preoperational inspection?

A. Usually with preops it's what you do after you do a wet clean. We're talking specifically about the Abbott factory in

Casa Grande. [redacted] Something was going on out there. And you -- an appropriate procedure would have been to take samples, [redacted] As I said, I would have preferred to see them testing directly for the pathogen. If they're testing for [redacted], you're testing for [redacted], but you're evaluating the factory environment to see whether it's in control to manufacture a sensitive product like the NeoSure.

Q. When you're doing this inspection that you've just now described, is the factory running?

A. The factory -- this should be done before the factory's running. In some instances you actually release the factory area back to operations, like actually get the test results back and then release it back. In some instances the manufacturing folks will start up and start making product and they'll make it at risk, but they won't put it in a package until they get the environmental sampling results back.

Q. Did Abbott -- when you reviewed your records, was there any evidence that Abbott did any kind of a preoperational inspection prior to the manufacture of this batch of NeoSure?

A. It was kind of -- it was kind of the opposite. [redacted]. What they did is they took environmental samples while the product was being manufactured [redacted]

drains in their dryer tower, and they just kept making product. They didn't use that information to do anything. They didn't shut down to clean. They just -- they -- they didn't do anything.

Q. Except make product.

A. Except make product.

Q. Okay. And you already started on this. My next question was going to be did you review any environmental test results that connect to the batch of powdered infant formula NeoSure that Jeanine consumed?

A. They -- so they had ////////// hygiene environmental samples that were taken on January 8. Nine were out of specification from the Abbott point of view. In other words, they were unacceptable from their testing standard. Two of the samples, drains // and //, reported as having E. sakazakii.

Q. When those kinds of findings are made, what should be the proper response to those running a powdered infant formula factory?

A. The -- well, it -- the real simple answer is you need to do something. And the do something can be a number of different things. You can shut down and clean. That's the obvious one. You can -- if you got product that's going on, probably the more normal approach would have been to shut down, clean, try to

bracket the product that was coming out of that area that was dirty, and then perform some enhanced way of evaluating that product to see if it's safety immunocompromised or not.

Q. What do you mean by an enhanced way?

A. You can test more samples. You can look at all your production logs and see if there's things going on that might have really led the product to being contaminated. You can go out and test your environment more to find out how contaminated it really is to see what your risk is. There's a number of different ways. None of these are very pleasant at this point in time, but that's why it's better to do this before you make the product instead of during or after.

Q. Now, you indicated you reviewed the review that Abbott conducted of this time period after they were notified that Jeanine got sick. Was there anything unusual in the production process that you saw in the information that you were provided?

A. Well, one of -- well, what I did is on the investigation piece, I tried to put together a time line, and I'm kind of operating at a disadvantage since I'm not part of Abbott. I can't lay my hands on logs, and I gotta sort of figure this out from the records about what was -- what was going on. But suffice it to say you can sort of get a rough feeling for what's happening. The product is obviously dried on the 8th. It was packaged the succeeding two days. When it was packaged, there was like a two-hour gap, and the packaging line was shut down

for some reason. That's the piece that I sort of saw that sort of raised some flags in my mind.

Q. Well, what -- why does -- why does a two-hour shutdown raise flags with you?

A. Well, these are big lots. We're talking about -- what'd I say? -- about somewhere in the neighborhood of 140,000 cans, and it's plus or minus, so it's a lot of cans to package in a relatively short period of time. The factories I've known, I mean, the best you could do is maybe 40,000 in a -- in 2 shifts. I mean, they were packing a lot of cans really fast. So having that amount of downtime, they wouldn't want to do it. They did it for a reason. Something happened. I mean, I don't know. It's just -- it's just -- it's a gap.

Q. In your experience what -- what happens when there's downtime?

A. Well, the obvious thing is it's down so you gotta start it up, you gotta shut it down. It means all the equipment has to be turned back on again. You got -- you know, this is not a small process. I mean, this is a big factory. Lots of stuff have to be turned on and off again. People -- they may have had a jam. Something may have broken. You don't know what's going on. But it usually involves worker contact which provides the opportunity to contaminate the product with a factory contaminant like E. sak.

Q. Let's go to the finished product testing. How did Abbott

test its finished product?

A. They had a -- they had their own way of doing this, so they -- the Infant Formula Act requires that you take sixty 25-gram samples, 60 cans, 25-gram sample from each can, per lot of product. And you need to test that for salmonella. And you can divide that up to four 375-gram chunks. So it's like fifteen 25-gram samples, fifteen 25-gram samples, like 4 of these.

[illegible] So I'm not arguing about that.

The problem is these folks just weren't using the right [illegible] I mean, the FDA has what's called the Bacteriological Analytical Manual, and it sets out in ever-so-clear wording what you need to do when you test powdered infant formula. You test it in lactose broth, not [illegible] This is a fundamental mistake. [illegible] So for salmonella they're using the

wrong stuff. For E. sak they were really using the wrong stuff. The FDA method of 2002 was put the product in sterile distilled water. The ISO method that came out in 2006 used phosphate buffered water, and that's basically what the FDA BAM method that was published as chapter 29 required. ////////////////// ////////////////////////////// // // // // // // ////////////////////// I was astounded. I really was. I had no -- I had no idea that -- once I looked at their -- at their records and I could see the ////////////////////////////////// ////////////////////////////// I went, oh, my God, this is -- it's a fundamental mistake.

Q. Did -- // That would be a total of how many grams that would have been tested for E. sak?

A. Okay. // // // // ////////////////.

Q. Is that enough finished product to test to -- considering the size of the lot and the specialty of the product?
A. Finished product testing -- the short answer is no. Finished product testing is for what is called verification. At this point if the product --
Q. First you're -- what's the purpose then of the finished product? Is that what you're going to go into?
A. Yes.
Q. Okay.
A. So finished product testing is for verification. It's a fancy word, but it means it should tell you what you already know; right? You made the stuff. It shouldn't have the organism in it. In this whole ES cronobacter FDA thing, the testing ended up taking on a connotation of almost being a critical control point. And that's not the case. You can't test -- // from a 70,000-can lot and have it tell you anything meaningful about a factory contaminant that's completely heterogeneous. In other words, there may only be one can that was contaminated that injured Jeanine Kunkel, but it happened. And that's -- but you're not going to -- the odds of you finding it in a testing scheme are just -- they're not there. And couple that with the fact that the testing scheme itself is incorrect and going to lead to false negatives, you're never, ever going to find it.
So the point being what you really need to do is to

look at your factory environment. That's what's going to tell you whether your factory has -- whether the product's going to be contaminated with enterobacter sakazakii or not.

And in Abbott's it's written right there. They have cronobacter in the dryer tower the day that product was dried. So their testing doesn't tell them anything. Their defective environmental sampling program said yeah, it was contaminated with E. sak, and it was in my opinion thoroughly contaminated to get results using the methodology they were using.

Q. How about the size of the sample itself? Accepting the -- what you've just testified that this is a verification, was there a big-enough sample tested for E. sak to accomplish that goal?

A. Well, okay. So then it gets -- so theoretically yes. They -- the way the FAO risk assessments eventually came out is that you needed to take 30 grams -- or 30 cans per lot. /////////////////////////// I think there needs to be a little bit of a practical piece of this in that these are very large lots. The lots that I was testing were much smaller, and, of course, that meant we just had many more tests for ES per lot of product or per lot of product as compared to what Abbott was doing.

It's just -- I think I've answered that question.

Q. And you're aware of the CDC testing of the open can --

A. Uh-huh.

Q. -- being negative.
A. Yes.
Q. And you're aware of the FDA collection of cans from the same batch, many of them manufactured at about the same time as the can that Jeanine consumed. You're aware of th -- and that was negative.
A. That was negative, yes.
Q. Does any of that change any opinions that you've given here today?
A. No, and I -- as I stated with my credentials, I do -- I teach folks. Companies hire me to teach them about food microbiology, about environmental sampling as well. And what I found is that many -- some of the companies that I work for are finding that their customers are demanding that environmental sampling data is provided with the COA. In other words, just the testing the product for salmonella isn't what they want. They want to see environmental sampling data for when the product was manufactured. That's -- that's the way things have progressed to the point where people are understanding that testing the finished product is verification and it doesn't tell you whether that product is safe or not. You're just meeting a compliance requirement.
Q. One last question. Do you have any -- any views or opinions with respect to the practice of manufacturing NeoSure in powder as opposed to not manufacturing in powder and

manufacturing it only as ready-to-feed?
A. I do. Abbott had a ready-to-feed product, a commercially sterile product, and they were also selling a powdered product. As the IFC paper Steve went through -- he didn't put this in big block letters, but powdered infant formula is not commercially sterile. It contains microorganisms. It can contain pathogenic microorganisms. The industry as a whole does not want consumers to know that. Abbott knows this. For them in my opinion to be making a powdered product that could contain ES at -- when they're selling an RTF product, a commercially sterile product, the very same product, I just -- I think it's irresponsible. That's my opinion.

MR. RATHKE: No further questions.

MR. REIDY: May I just have a moment, Your Honor?

THE COURT: You may.

CROSS-EXAMINATION

BY MR. REIDY:
Q. Dr. Donnelly, my name's Dan Reidy. We've not met; is that right?
A. That's correct.
Q. Now, as you come here to testify, you came to testify fairly; right?
A. Correct.
Q. You're going to have to lean forward to the microphone a little bit more.

A. Yes.
Q. And you worked very hard to get your facts right that had anything to do with any of the opinions you offered here today; right?
A. Yes.
Q. And do you have your facts right?
A. I believe so.
Q. And you've been in the industry for a long time with respect to working in powdered infant formula, is that right, or at least as of 2007 when you left Wyeth?
A. Yes.
Q. And you began in 1983 I think working at Wyeth?
A. Yes.
Q. And you worked at their Vermont plant; is that right?
A. Yes.
Q. And that produced powdered infant formula the whole time you were working there?
A. Yes.
Q. And did you produce a powdered infant formula that was equivalent to NeoSure, that is, for preemies?
A. Yes.
Q. And you also produced other kinds of powdered infant formula such as healthy baby powdered infant formula; right?
A. Yes.
Q. And you were the lab operations quality assurance manager

at that Georgia plant for a while?
A. Correct.
Q. And you had that position in 2002?
A. I don't believe so. I think I was at -- I was working for corporate at that time.
Q. Beginning when?
A. I can't remember. It was right in the transition period there. It's like -- there was a period of time when I was -- for almost three years where I was a corporate resource but I was located at the Georgia factory.
Q. And what period of time was that precisely?
A. Somewhere between 2001 and 2003.
Q. And when you were working as a corporate resource, did you have anything to do with the safety of the powdered infant formula at Vermont?
A. Yes.
Q. And was it still your responsibility?
A. It was technically not. I had oversight for it, yes. The answer is yes.
Q. So you oversaw the people with the direct responsibility.
A. Yes, yes.
Q. But you still maintained responsibility for the safety, the bacteriological safety, of the products that were coming out of the plant; right?
A. That's correct.

Q. Now --

MR. REIDY: Excuse me one minute.

Q. So you talked in your direct testimony about the Portagen outbreak problem in Tennessee with the Mead Johnson product; right?

A. Correct.

Q. And when that happened, you were -- had responsibility for quality assurance, the microbiological quality assurance, at the plant at which you were working; right?

A. Yes.

Q. And you talked in your testimony about how the FDA came out and they announced that they were going to come to each of the powdered infant formula manufacturers and do an inspection; is that right?

A. That's correct.

Q. And in due course they came to Wyeth to do an inspection; right?

A. They did.

Q. How'd you do?

A. We were the first one they visited, and it was like right around September there.

Q. I'm sorry. How did you make out? Did your inspection pass, or were you found to have E. sak?

A. Our product contained E. sak in one sample.

Q. And was it a single lot that contained E. sak?

A. Yes, that the FDA took at that time, a single lot.
Q. And when you say the FDA took at that time, you mean the FDA came in, found that single lot containing E. sak, and when you say took it, you mean they told you you couldn't ship it.
A. No, they didn't tell us that. They reported the results as positive, and we agreed that we would not ship it.
Q. So what did you mean when you said took it?
A. I guess I -- I'm . . .
Q. Okay. No significance, in other words.
A. No significance.
Q. Okay. So that was a product I think you indicated during your direct examination that had never shipped; is that right?
A. That's correct.
Q. So did you then start looking at other lots that you'd produced under your supervision?
A. We did.
Q. Did you find any other E. sak?
A. The -- we being Wyeth, yes.
Q. And did you do a class 1 recall?
A. I believe at the end of the time period when we were investigating we did take the product back out of the market in a class 1 situation.
Q. And class 1 means what?
A. You want to get it out there because you think there's a potential safety problem with the product.

Q. And your potential safety problem was you had shipped product which contained E. sak.
A. We had shipped product, yes.
Q. Were there other recalls, class 2 recalls?
A. You're going to have to help me out here. Other -- when? I mean, I don't know.
Q. I'm sorry. Right in that time frame when the E. sak thing was breaking, did you have to take -- you took the one -- you didn't ship the one lot that the FDA found had E. sak in it while you were there; right?
A. Correct.
Q. And then you found another lot that you had to go out and pull back off the shelves because it had E. sak in it; right?
A. Yes.
Q. Did you find any other lots with E. sak in them?
A. There was a considerable amount of product, almost three months' worth, that was in our control.
Q. And it had E. sak in it; right?
A. Different pieces, parts, but yes.
Q. And so you had basically three months of product that had E. sak in it that you had to get back off the market or take off --
A. No, no, no, no, sir, that's not correct.
Q. So let me -- okay. Let me split it up then so that I do this right. You found some product such as the one that the FDA

discovered in their exam. That was in your product still -- still hadn't shipped when the FDA found that it had E. sak; right?

A. The FDA found the original positive. We conducted a thorough investigation, and the investigation ultimately included looking at some product that had already shipped to market which got us into the position where we wanted to get the product back.

Q. Okay. So the FDA's finding of the E. sak in your product was on product that hadn't yet shipped, so you were able to reject that.

A. Right. So more to the point, actually the recall --

Q. Actually the point's in answering just the question I put to you. So my question to you was the FDA, when they found the E. sak, that was in a lot that you hadn't shipped yet, so you could reject it; right?

A. Correct.

Q. And when you did more investigation of your own lots, some of those also hadn't shipped; right?

A. Correct.

Q. That is, some of those lots that you found E. sak in; right?

A. Correct.

Q. And then you also found E. sak in some lots that had shipped, and you recalled it; right?

A. Correct, and that was Wyeth found that, not the FDA.
Q. Correct. So the FDA only finds it in one. Wyeth then looks at the rest and acts appropriately; is that right?
A. Tells the FDA that we're responsible citizens and we think we should recall the product.
Q. Sure, because it had E. sak in it; right?
A. We were -- we were very concerned about the safety of our consumers.
Q. You found E. sak in the product; right?
A. Which is why we recalled it. Yes.
Q. Thank you. After that flurry of activity in 2001, 2002, you still maintained responsibility for quality at the Vermont plant; right?
A. No, I was much -- after 2002 -- by 2003 I was pretty much a corporate resource. I had oversight for all of the Wyeth factories and labs from an oversight point of view.
Q. Oversight for quality assurance on microbiological purity?
A. Product safety, yes, the lab ops piece, anything to do with micro.
Q. So you were responsible for product not only in Vermont but at other places.
A. In the way you're terming it, yes.
Q. Well, you term it any way you want. Were you -- did you have responsibility for product safety in the Vermont plant and beyond?

A. Yes.
Q. Now, at the time of the recalls, both the FDA-instigated recall and your own instigated recalls in 2002 from the plant, did you find environmental positives for E. sak?
MR. RATHKE: I'm going to object to the question as misstating the evidence.
THE COURT: Overruled.
A. Did we find environmental positives? Yes.
Q. What kind of environmental positives did you find?
A. I don't know how to respond to that.
Q. Where'd you find them?
A. We found them in wet areas relative to the dryer. It was -- it was surprisingly harder to find the organism than it would appear.
Q. And where -- and more specifically, can you tell me where you found it?
A. I really don't remember.
Q. And you had -- the FDA obviously gave you an EIR, right, Wyeth?
A. Correct.
Q. And what's an EIR? Can you tell the ladies and gentlemen of the jury?
A. It's called an establishment inspection report.
Q. And that's sort of the follow-up to them finding E. sak in your product?

A. Right.
Q. By the way, when they found E. sak in your product, that was after Portagen; right?
A. That was.
Q. And they sent you a note saying they were coming to inspect your plant; right?
A. They did.
Q. So it wasn't a surprise that E. sak was really important at the time after the Portagen outbreak and after you had notice that the FDA was coming to look at your plant for E. sak; right?
A. You -- no.
Q. Now, specifically as you reviewed the reasons why under your supervision E. sak had been found in a bunch of lots in 2002 of Wyeth's powdered infant formula, did you find that there was a problem with the agglomerator process?
A. Yes.
Q. And was the specific problem that during the agglomerating process you had people, workers, open up a access panel into the agglomerator and put their bare hands in and manipulate the powder? Is that what you found?
A. No.
Q. What did you find?
A. We found that the agglomerator was not receiving a sanitizing rinse and that you could quite easily track contaminated product to wet cleaning cycles of the agglomerator

and that once the sanitizing rinse was used the ES contamination disappeared.
Q. And did you have circumstances where it was routine during the Wyeth manufacturing process for workers to open a panel in the agglomerator and put their bare hands in there?
A. No.
Q. Did you ever have that?
A. No.
Q. So it was never a circumstance where workers opened a panel in the agglomerator and reached in and manipulated the powder?
A. I -- I mean, I was at the company a long time. I think I've observed that as a training exercise at one point, but as a routine thing, no.
Q. So you saw people being trained to reach into your agglomerator with their bare hands and manipulate the powder.
A. It was more like when the agglomerator was first -- was first commissioned they had some crews from Ireland that were familiar with operating it, and they were trying to show people what the proper powder would actually look like. You know, it's gotta have a certain powder -- the particles have to be a certain size and so on.
Q. But you were aware that people had opened -- during processing that people had opened that, stuck their bare hands in, and manipulated the powder; right?
A. In what time frame? Like 1980 -- 1990 something.

Q. And had that been stopped since 2002?
A. Yes.
Q. And you had stopped it?
A. Well, I wasn't responsible for production activities, but yes, that was not a practice that I observed at that time.
MR. REIDY: One moment, Your Honor.
Q. Well, let me ask you this. During the rest of the time that you remained at Wyeth, were there occasions when you found E. sak in finished product?
A. Occasions. Yes.
Q. And is your best estimate that it was -- well, can you give me an exact number how many times you found it there?
A. No.
Q. And this was under circumstances where you caught the E. sak in the finished product before it was shipped so you didn't have to do a recall; is that correct?
A. Yes.
Q. So there were no more recalls while you were there, but your finished product testing did identify E. sak on some occasions.
A. Correct.
Q. And what did you do when you found the E. sak in the finished product?
A. It was destroyed.
Q. And how many times did that happen? Do you have a number

you can estimate?
A. I have no -- I don't. No, I have no memory of that.
Q. So the estimate you gave in your deposition, was it not, was zero to ten, some number between zero and ten?
A. Some number. I don't know. I don't know.
Q. But you remember that it did happen.
A. It wasn't a hundred. It wasn't zero. I don't know.
Q. It's kind of a big event when you have to destroy a whole lot because somebody finds E. sak in the finished product; right?
A. Oh, it gets to be painful. It wasn't that frequent.
Q. But you know it was some number of times that it happened; right?
A. We've agreed to that, yes.
Q. And by the way, when that happens according to your testimony this morning, that means there's something very wrong with your production process at Wyeth; right?
A. There would have been a complete investigation to find what the cause was, yes.
Q. So there would have been something very wrong with your process if you find it in your finished product.
A. Things go wrong in processes. That's why you have all the quality systems in place you have. The whole idea is to make safe product.
Q. Something was very wrong for E. sak to get into your

finished product; right?
A. I wouldn't use the terms very wrong. Something was wrong, yes.
Q. And you told us that the finished product testing isn't any kind of a control point where you check on things that you can really -- you're not relying on that in order to make safe product; right?
A. That's correct.
Q. So in your case, though, had you not done the finished product testing, you would have shipped product with E. sak; right?
A. We had done -- probably, yes.
Q. Sounds like kind of a pretty controlled -- critical control point to me. Does it sound like a critical control point to you?
A. No, it's not. Doesn't meet the definition.
Q. Okay. But if we're talking about just laymen's terms, it was a pretty good thing for the public that you guys did a finished product test before you shipped the stuff that had E. sak in it; right?
A. Yes.
Q. Now, do you know that Abbott did not have any E. sak discovered in its plant when the FDA came through it in 2002?
A. I have no knowledge of that.
Q. And did Abbott inspect -- or I'm sorry. Did the FDA in

2002 inspect the plants of all the powdered infant formula manufacturers?
A. They do on a yearly basis. I have no direct knowledge of what happened at the other factories than the one that I was based at.
Q. And you put up some -- or Mr. Rathke put up and asked you about some documents that the FDA sent around about that; is that right?
A. That's correct.
Q. And this was one of the documents that you went through; is that right?
A. Yes.
Q. And it lists product types; is that right?
A. Yes.
Q. And among the product types it lists are preterm formulas; right?
A. Yes.
Q. And the preterm formulas, that means formula that is -- product -- powdered infant formula that is prepared for premature infants; is that right?
A. Yes.
Q. And Wyeth had such a product; right?
A. Yes.
Q. And you're the one of the four there, aren't you?
A. I don't know.

Q. Well, do you recall that of the various products that were -- or the various lots that were recalled one of them was your product for --
A. I don't recall.
Q. -- premature infants? I'm sorry.
A. I don't recall.
Q. Okay. You probably should wait till we finish so that we don't talk over each other for the court reporter. But over on the right-hand side as far as the full-term formula, do you recall whether Wyeth's full-term formula was one of the products you had to recall?
A. Honestly don't remember what the product was.
Q. Now, a significant part of your direct testimony was criticizing Abbott's processes; is that correct?
A. I'm not sure how to answer that. I mean, a significant portion of my testimony was responding to comments about the IFC papers and some of those things.
Q. Well, you talked about Abbott's processes; right?
A. I did.
Q. And you were critical of them, weren't you?
A. Yes.
Q. So a big hunk of your testimony was criticizing Abbott's processes, wasn't it?
A. In your words, yes.
Q. And before you did that, you made sure you had your facts

right.
A. I tried to.
Q. Now, by the way, while -- let's say after the 2002 problems at Wyeth and the recalls, after that, did you get to where you had it figured out how to make powdered infant formula without E. sak in it?
A. What's the time frame again, please?
Q. After the 2002 -- actually let's set aside both the 2002 problems and this number of times when you caught it yourself in the finished products, and let's only address circumstances about products shipping. So after that flurry of activity in 2002, what's your level of confidence that Wyeth didn't ship powdered infant formula with E. sak in it?
A. High.
Q. And have you indicated that your confidence was a hundred percent?
A. I know what we released, and it didn't contain E. sak. I know I was doing product compliance, so I know we had no adverse complaints for that for infections relative to the organism, so I would say yes, I'm confident.
Q. And you've -- well, let me put it this way. You're 100 percent confident that you didn't ship any product with E. sak in it; right?
A. Yes.
Q. Okay. So it's definitely possible to have a plant with

powdered infant formula where you can, despite the risks, proceed in such a way that a highly qualified quality engineer such as yourself and microbiologist -- I'm sorry, and food science Ph.D. can be 100 percent confident that the powder shipped did not contain E. sak.

A. Okay. You're drawing me into the hundred percent thing. I don't think you can be a hundred percent certain of anything.

Q. But you've testified previously that you were a hundred percent sure, haven't you?

A. Again, you'd have to read the depositions. If I have said that, I will stand by the statement.

THE COURT: Just a second. You can certainly use the deposition to impeach him. I'm not going to allow you to put it on the screen unless you --

MR. REIDY: I'm taking it off this screen, Judge.

THE COURT: Okay. Thank you. Thank you.

MR. REIDY: For sure I understand.

BY MR. REIDY:

Q. I'm going to show you page 68 of your deposition.

THE COURT: Yeah, that's exactly what I wasn't going to let you do.

MR. REIDY: Oh, I'm sorry.

THE COURT: And here's why. Unless it's isolated -- and lawyers have done it before. But the problem is it's never isolated to just the question and answer. If it was, I wouldn't

have a problem with it.

MR. REIDY: Sure.

THE COURT: So the jurors then can read other portions of the depositions. That's why.

MR. REIDY: And I completely agree, Judge. I meant to hit blackout.

THE COURT: Okay. Thank you.

MR. REIDY: No problem at all.

BY MR. REIDY:

Q. So I'm going to see if we can get this so that you can read page 68. Why don't you read that to yourself starting at . . .

A. Okay. So what are you asking me about?

Q. Just hold on a second if you would. Actually let me take you over to -- takes a while to track the question.

MR. REIDY: One moment, Your Honor.

THE COURT: That's fine.

Q. Okay. So on page 68 at line 16, do you see that beginning really at line 15?

A. Okay.

Q. Read lines -- read that to yourself, and then I'll turn the page for you, and you can read the top line of the next page.

A. Okay.

Q. And then at the top of the next page, do you see that question, and do you see that answer?

A. Yeah.

Q. So now I ask you again do you have 100 percent certainty that after the recalls of 2002 Wyeth under your supervision did not ship any product with E. sak in it to a 100 percent level of certainty?
A. The best of my knowledge.
Q. And that's because you did it the right way at Wyeth; right? That's why you're confident?
A. We may -- I had a -- I was lucky in having a committed management, and we made every effort possible to produce safe product.
Q. Now, you've referred I think several times during your direct examination to the number of cans in the lot from which the can which Jeanine Kunkel got was taken; is that right?
A. Yes, yes.
Q. And you said it was split because part of it was sent to Canada and part of it was sent to the U.S.; is that right?
A. From the records that I had looked at, that would be correct.
Q. And you described that as a very, very large shipment; is that right?
A. Yes.
Q. And you approximated it at 2 shipments of about 70,000 cans; right?
A. It's a ballpark figure based on the cases, but yes, I think that would be roughly correct.

Q. And you went so far as to say that that was too big of a shipment from a safety standpoint; is that right?
A. No.
Q. Well, didn't you say that it's a bad practice to have such large shipments?
A. No.
Q. Didn't you say the shipment was too big to fail?
A. Yes.
Q. And when you say something is too big to fail, you mean that it's so big that people might overlook problems with it rather than suffer the economic loss of having to crater such a large shipment; right?
A. That's your words.
Q. What did you mean by too big to fail?
A. It was a large entity of product that would present problems internally for how to deal with it if there are quality issues.
Q. And I'm pretty sure that means what I just asked you; right? That means you're saying it was so large that people might resist shutting it down if it had a problem; right?
A. Okay. Yes.
Q. When you say okay, is that your testimony? My testimony is unimportant. Is it your testimony when you said the lot of 140,000 cans was too big to fail that that meant that it posed an additional risk that because of its size and the economic

consequence of that size people might not treat it the same way they should with respect to safety issues?
A. Yes.
Q. I'm going to take Exhibit 2052, Defendant's Exhibit 2052, and I'm going to go to page 5 of that exhibit. Can you see that on your screen?
A. Yeah.
Q. And does it indicate what the size of the two segments of batch 61281 was? See the batch size number over there?
A. Yeah, I know. Is that cases or cans? What is that?
Q. That's cans.
A. Okay. So you got 20,000. You got almost 80,000. So you got 100,000.
Q. So where did you get the number 140,000 in your too-big-to-fail lot?
A. When we were looking at the shipping records, it appeared that there was like 12,000 cases that were shipped to Canada and like 13,000 in the U.S., so I just sort of figured 6 cans per case and came up with it that way. It was a rough calculation.
Q. If this document in front of you is accurate as to how many cans there were, your rough calculation was an exaggeration of 40 percent; right?
A. Yes.
Q. And do you have any reason to believe that that number, the hundred thousand you see there, is inaccurate?

A. You're -- I -- you're providing me with this information. I have to assume it's correct.
Q. Okay. I just put on the screen the document you were using earlier; right?
A. Yes.
Q. And that's what I think you described correctly as a rough schematic as to how the process works as you understand it at Abbott; right?
A. Yes.
Q. And you've divided the wet side and the dry side into colors; right?
A. Yes.
Q. And have you put all of the critical kill points on here?
A. I put the -- I attempted to put in there where I thought your pasteurization process was, so that would be the steam and the arrow and the 250.
Q. And do you know whether or not there's another heating of the liquid that gets up to a point that would kill bacteria?
A. You're going to have to be -- help me out here. You need to be more specific.
Q. Well, do you know as you sit there looking at this diagram if there's anyplace else on this diagram where the liquid is brought to a temperature of, say, ////////, something like that?
A. Do I know of a place on this diagram where the liquid's brought to a temperature of ////////// I could guess and say

perhaps there are places.
Q. But when you were putting the diagram together, you didn't look for those.
A. No, I read the material that I had from both your expert who evaluated the process and the material that I was provided that described your process, and that's how I constructed the flow diagram from.
Q. And did you have some testimony about dry heat and how it doesn't kill?
A. I did.
Q. And what was the point of that testimony?
A. Point was that dry heat does not kill in the same manner that wet heat kills.
Q. And did you testify about any misunderstanding that Abbott had about that?
A. I did.
Q. And what was your testimony about the misunderstanding?
A. The misunderstanding was that inlet temperature heat is sufficient to kill bacteria in the way that a -- your pasteurization step does.
Q. And who had that misunderstanding?
A. Sharon Bottock did.
Q. Okay. Now, I'm going to give you a different pronunciation. Sharon Bottocks.
A. Okay. Sharon Bottocks.

Q. Bottock, sorry, no s. As you can imagine, it's a delicate subject.

So you said that Sharon Bottock seemed to think that the heat in the dryer would be a kill step? Is that what you were saying?

A. I never said that.

Q. Okay. I'm sorry. What did you say her misunderstanding was?

A. I don't know if there's a transcript, read it back. I don't know what I said exactly relative to that. The information was provided during my earlier testimony today that -- about the use of dry heat as a critical control point in a powdered manufacturing process and the fact that it could not be used as a critical control point because it wasn't killing all of the bacteria. It wasn't something that was sufficient to do that, and I believe I was pretty clear in describing it in that way.

Q. And your point was that Sharon Bottock did not correctly understand that; is that right?

A. From what I read in the deposition, no.

Q. And can you give me any idea in the deposition where you were talking about that she seemed to misunderstand that dry heat would kill the bacteria?

A. I don't have the deposition in front of me.

Q. Can you tell me what she was describing? Was she

describing something in the dryer process?
A. My recollection, it was the -- they were talking about inlet temperatures to the dryer which are high. They're very large numbers. It's like your oven at home.
Q. And so this caused you to conclude that she did not understand that high dry heat temperature wouldn't kill the bacteria in the way that high temperatures applied to the product when it was in liquid form; is that right?
A. Correct. That's a physical law.
Q. Okay. And so that was one of your criticisms is that the quality assurance manager at Casa Grande didn't seem to understand that the high temperature at the head of the dryer wouldn't be a bacteria kill point.
A. Your words. I never said that.
Q. Okay. I'm sorry then. What was your point in describing her misunderstanding?
A. That it was -- that it wasn't sufficient, that they seemed to think that that was going to create a clean and a dryer that was E. sak free, the high temperatures.
Q. And that's what you thought she was saying in her deposition.
A. Yes.
Q. I'm going to see if I can find the part where that discussion was occurring.
MR. REIDY: Excuse me one moment, Your Honor. I just

have to come up with a clean copy.

THE COURT: That's fine. Thank you.

Q. All right. I'm going to show you page 45 through 48. I'll direct your attention to part of it. Can you see it on your screen?

A. Okay.

Q. Can you read it?

A. Yeah, I can. Where are we?

Q. Let's go to page -- the bottom of 47 -- I'm sorry -- yeah, the bottom of 47. And why don't you read to yourself from line 20 on the bottom of 47 down to line 17 of 48 and see if that was any part of what gave you the understanding that Miss Bottock did not understand the -- the dry heat and heat in the dryer wouldn't kill bacteria.

A. It seems that's what she's saying. She's saying if there's bacteria --

Q. I don't want you to read it. Is this part of -- is this part of what you came to the conclusion that she thought the dry heat would be part of that?

A. Yes.

Q. Okay. And can you read that one again? Actually I can probably make it a little bit bigger.

MR. RATHKE: Where are we?

MR. REIDY: I'm sorry. We're at 98.

Q. So if you can, read beginning at line 21 on 97 and going

down through the bottom of 98. And then I'll actually give you a little bit of 99 to look at.

A. Okay. Okay.

Q. And then just read the top few lines on 99.

A. Yeah. Okay.

THE COURT: Dr. Donnelly, when you respond, could you get a little closer to the microphones? Thank you.

A. Okay. What was the question?

Q. Okay. Now -- my question now is do you now have a better understanding that Miss Bottock was talking about ////////////// //?

A. I just read all that, and I didn't come away with that at all.

Q. All right. Well, let me ask you a different way. Do you know from your study -- well, let me strike that.

You put on a high temperature point on the liquid side of things in your diagram, the one that says 250 degrees there; right?

A. Okay. I'm -- I'll answer your questions. What is it you're asking me?

Q. You put on your diagram a kill point, a high temperature point, on the liquid side of the process at 250 degrees there between the second and third blue box; right?

A. That is -- that should be -- and like I say, I haven't walked your process, but that would be your Pasteurized Milk

Ordinance legal pasteurization step. That is your critical control point that's in your HACCP plan.

Q. Okay. And did you see a critical control point that's further down the process?

A. No.

Q. So you didn't see then -- if we look at your diagram and you look right where the line comes through between the evaporator and the dryer, you see that?

A. Yes.

Q. And did you understand the testimony of Miss Bottock to be that you just read that [redacted] Did you understand that?

MR. RATHKE: Object to the question. Hearsay. It's Miss Ghezzi that's doing all the talking there.

THE COURT: Overruled.

A. Okay. What are you asking me again?

Q. Did you -- do you now recall -- having refreshed your recollection from the Sharon Bottock deposition that you were basing your testimony on, do you now recall that Miss Bottock described [redacted]?

A. No. I cannot make heads or tails out of what was said in that deposition relative to that subject.

Q. Okay. So you were -- you thought you understood it well enough to come in here and tell the ladies and gentlemen of the jury that she was wrong because she thought hot air killed the bugs.

MR. RATHKE: Objected to as argumentative.

THE COURT: Overruled. You may answer.

A. I -- that's -- not only that, but your -- Dr. Wiedmann also referenced the dry/hot air in his expert report.

Q. We're talking about the misunderstanding that you ascribed to Sharon --

A. I --

Q. You have to wait till I finish my question. We're talking about the misunderstanding that you said the head of quality assurance had at Casa Grande with respect to whether or not there was a // Now, didn't you come and testify to that?

A. Okay. So you're asking me if I said that the Casa Grande quality head did not understand that there was a dry heat kill step in the Abbott process.

Q. No, that's not what I said. I'll try again if you can't keep track of my question.

A. I can't.

Q. Okay.

A. I can't read the deposition. I can't make heads or tails out of that line of questioning, and where you're going with

this I don't have any idea.
Q. Well, let's go to that since you've said that. It's not important that you know where I'm going either. Let's go back to the part about where you can't make head or tails out of that testimony. Is that your testimony now? You couldn't make head or tails about what the testimony was about Sharon Bottock talking about the ////////////////////////////////////
A. The exchange that I read in the deposition was very hard for me to follow technically. I could not make a clear under -- clear -- //////////////////////////// To me my interpretation was it was dry. I -- it's very hard even seeing it again to figure out exactly what was said.
Q. Okay. So in a state of confusion as to what Sharon Bottock was saying in the deposition, you felt it was clear enough so that you could come and tell us and this jury that she didn't understand how her process worked; right?
A. Your words.
Q. No, no. Those were your words this morning. Isn't that your testimony this morning?
A. I never testified that she did not understand her process.
Q. You didn't.
A. I did not do that. I said that she -- my comments related to understanding the difference between wet and dry heat.
Q. I see. So what you said was she didn't understand that the temperature just as it was going into the dryer, the dry heat,

that she misunderstood that that was a kill step; right?
A. Okay. You're completely leaving me behind here. What goes in the dryer is liquid product. Air interacts with product after the liquid is in the dryer; okay? If you're talking about things that --
Q. I'm going to interrupt you --
A. If it goes to an evaporator, that line probably includes some kind of a dryer preheater, so you're not going to dry product that's cold. So, I mean, that would be my understanding of a process.
Q. So is it possible that when Miss Bottock was describing in the deposition the [redacted]?
A. I don't know. I cannot understand that interaction and determine what technically was said or what was not said relative to that. I had one interpretation. There are probably others. It wasn't a very coherent description of the process.
Q. So you took the one interpretation that was that she didn't know what she was talking about and came in and testified to this jury about it.
A. And it's also the one that your expert Martin Wiedmann said in his report.
Q. I didn't ask anything about the expert. I'm talking about what you said about Sharon Bottock this morning. So --

A. I didn't say anything about Sharon Bottock this morning.
Q. Now, if, in fact -- I'm sorry. You said there is no critical control point of liquid heating just before the product goes into the dryer in the Abbott process; is that right?
A. That's correct.
Q. And you studied Abbott's critical control points because you were critical of them; right?
A. Okay. That sounds like --
Q. It's two uses of the word critical. Want me to move it around? Let me withdraw the question.
A. The --
Q. I've withdrawn the question, so I'll put another question, try and make it clearer for you. Do you know if there is a critical control point where the liquid is heated to a point high enough to kill bacteria in the dryer building before the liquid is sprayed into the dry heat of the dryer?
A. No, I don't.
Q. And you studied Abbott's critical control points, did you not?
A. I -- the information I was given was not incredibly detailed in nature, but I looked at the process again as I've explained to you. I can only look at what you folks give me, and I came up with this as a in-general description of your process.
Q. And did you get enough information so you could figure out

what the critical control point was for the heating of the liquid to kill the bacteria?

A. Like I say, my understanding is that your ////////////, //.

Q. Okay.//,

//, //, ////////////, I'm not knowledgeable about that.//,

//, //, //,

//, ////////.

Q. How much -- how many grams of the finished product of the lot which eventually ended up producing the can that was fed to Jeanine -- or part of which was fed to Jeanine Kunkel, how many grams was in finished product testing?//,

//, ////////.

Q. And how do you know that?

A. I read your salmonella procedure and your compositing scheme, and that's where you're taking ////////////////, Are you suggesting it's different?

Q. Once again, I get to ask the questions.

A. Okay. Go.

Q. So what you're saying is that the reason you believe ////, ////, of the lot relative to Jeanine Kunkel's can was tested is because that's what you read in the procedures.

A. Yes.

Q. Did you study the lot records of the specific lot that you're talking about?
A. We looked at it. There would have been -- as you pointed out, they had a Canadian lot and a American lot. So ////// would have been tested for each of those.
Q. So the production lot included both those; right?
A. Okay. We're going to have to decide what a definition of a lot is. And from Abbott's point of view, it's either what -- it's when they changed over to package for Canada they created a new lot, so there's two lots here. From a production point of view, from a drying the powder point of view, it all came out of the same drying lot.
Q. So I use the term production lot to cover both the Canadian and the -- the parts of the lot that were eventually shipped to Canada and the U.S. Is that okay with you for vocabulary?
A. Yes.
Q. So the production lot from which Jeanine Kunkel's can came, how many grams were tested of that in finished product testing?// // ////.
Q. And with respect to your earlier testimony, you were critical that ////// of finished product testing is insufficient; is that right?
A. The industry standard as espoused by Dan March for a presence/absent test was 1,332.
Q. 1,332 grams?

A. Correct, yes, per lot.
Q. And this morning I recall correctly that you did come and say that the testing of the Abbott lot that went to Jeanine Kunkel was inadequate because ////////////// were tested; right?
A. That's one of the reasons, yes.
Q. And you've now acknowledged to us that, in fact, from the production lot from which Jeanine Kunkel's can came, the amount tested was actually //////////; right?
A. Yes.
Q. And ////////////////////////// -- what was your number?
A. 1,332.
Q. Was ////////////// right?
A. Except they should have tested 1,332 for each lot. You had 2 lots. You needed to test 1,332 for each lot. ////////// ////////////////////////////////// You're doing it on a lot that's going to market.
Q. So it's written somewhere that the 1,332 is not based on a production lot, it depends on where you send your cans?
A. It isn't your batch records. If they're doing a separate test for each lot, you should be doing the same separate test.
Q. In the case of the production lot of the amount -- well, strike that.
The 1,332, that's talking about production lots, right, the standard of 1,332 being the number of grams that should be tested?

A. When I see lot -- when I think of a lot, it's what you use as a release entity, what are you releasing based on, and that would be 1,332 per quantity that you're releasing to the market. So you had 2 quantities that you released to the market.
Q. So you're saying that the 1,332 is controlled by whether we send some of our cans to Canada and some of them to the U.S. as opposed to what was the entire production lot inside our system?
A. That's Abbott's quality system, not mine. I mean, it's what they do. I mean, that's the way the batch records are set up.
Q. Okay. But you would agree with me that for the production lot from which Jeanine Kunkel's can came, ////////// were tested at Abbott.
A. Yes, for the gross lot of powder that was dried, we tested //////////.
MR. REIDY: One moment, Your Honor, please. I'll only tell Your Honor that I'm skipping a couple of things which should be good news for everybody.
Q. You offered criticism of Abbott's HACCP program, did you not?
A. In my original written report I did, yes.
Q. And did you say anything this morning about it?
A. No.
Q. And with respect to Abbott's production facilities, they are inspected by the FDA, are they not?

A. They are.
Q. And they're inspected on at least an annual basis?
A. Correct.
Q. And you've seen records of FDA inspections of the Abbott powdered infant formula plant at Casa Grande?
A. I've read several.
Q. And in addition to that, Abbott has inspections from Cook and Thurber too as well; right?
A. That's correct.
Q. And they had inspections from Cook and Thurber in 2007 and 2008, say our relevant time period for this case; right?
A. If you say so, yes.
Q. If you don't know, you can say you don't know. You don't have to accept --
A. I haven't reviewed that information specifically, but yes, I believe that's the case.
Q. Okay. And in your view Cook and Thurber is the gold standard of third-party auditors; right?
A. They're well recognized for performing audits, yes.
Q. And you, in fact, have referred to them as the gold standard for third-party audits.
A. Okay. Yes.
Q. That's what you think; right?
A. Yes.
Q. Okay. I'm going to put up what's been marked as Exhibit

1012A -- I'm sorry, 1012B. And, Dr. Donnelly, do you recognize that as a Cook and Thurber audit report?

A. Okay. Yes. Yes.

Q. And you're familiar with Cook and Thurber?

A. Yes.

Q. And until 2007 when you left Wyeth, had they done audits of Wyeth's powdered infant formula?

A. I don't know.

Q. You don't know whether they ever did?

A. Don't know.

Q. Okay. And they audit a number of things when they come in; is that right?

A. Well, yes, they -- yes.

Q. Okay. And do you know how they're sent in? I think are they sometimes sent in by large customers?

A. Yes.

Q. And I think you referenced -- well, maybe you did, maybe you didn't. But they're often sent in by very large purchasers of powdered infant formula; right?

A. If you say so.

Q. Well, do you know?

A. I believe I know, yes.

Q. Okay. So what do you know?

A. I know that Cook and Thurber came in to audit the factory originally for Costco.

Q. At Wyeth or at Abbott?
A. Abbott.
Q. And Costco would fit my description of a large purchaser of powdered infant formula.
A. It would.
Q. Turning to page 2 of the audit, that's Cook and Thurber's scoring of the audit?
A. Uh-huh.
Q. And with respect to those numbers, section B is the HACCP management; right?
A. Yes, yes.
Q. And I'm not sure we've done this. Will you describe what HACCP stands for, the acronym?
A. Hazard Analysis and Critical Control Point.
Q. Okay. And so we were discussing earlier the heat point being a critical control point for microbiological control. That would be what we mean by a critical control point; right?
A. That's a critical control point.
Q. Okay. And when they say critical control point, they mean something that is where you're relying on it to accomplish whatever it is it's supposed to be accomplishing.
A. Critical control point is a point in your process where you can reduce, eliminate, or control the hazard.
Q. And in the case of a microbiological hazard, at least while it's in the liquid form, heating the liquid above the level that

the microbe can survive is, therefore, a critical control point; right?
A. If you're able to document that, yes.
Q. And ordinarily in the course of a processing of a batch, you'd expect to find documentation of the temperatures; correct?
A. No. On a critical control point you actually need monitoring data. You have to have data indicating that in this -- whatever your heat -- whether it's going to be a combination of both time and temperature that it was delivered to the liquid as it's supposed to to control, reduce, or eliminate the hazard.
Q. And Cook and Thurber gives the Abbott Casa Grande powdered infant formula plant or infant formula plant a 97 percent in HACCP management; right?
A. That's what it says.
Q. And you know 97 percent to be a pretty good score; right?
A. I disagree with that.
Q. Okay. What do you think?
A. I think for the industry leader that's part of a pharmaceutical company they should be having hundreds across the board here pretty much.
Q. And I think I asked you this already, but do you have any familiarity with Cook and Thurber scoring and reports at Wyeth?
A. No.
Q. And have you seen Cook and Thurber's scoring reports at

other infant formula plants?
A. No. I'm pretty -- I'm familiar with these kind of audits, and actually one of my client activities is getting them prepared to go through some of these audits. I know what they look for. I'm just saying I'm not impressed by that. I'm particularly not impressed if you go back and you read this report and the previous one, 85's a fail. Their first Cook and Thurber audit, they had a 92 across the board which is like barely getting your nose above the -- above the -- above passing. So you're asking me if I'm impressed. I'm not impressed.
Q. And with respect to the 97 that we were talking about here, you don't think that's meant to be a good score.
A. It -- usually if you're -- there's another 3 percent out there. They're wanting more.
And then the other piece with these audits is they're not content driven. They're just looking to see do you have one and how is it written and are you following, you know, usually your procedures. There's not a lot of content going into that. They're just checking to see if you've got a pest control program, if you have a sanitation program. They're not looking at the content part of it.
Q. So according to you, they don't look at all of the content of your HACCP program?
A. Not all of it, no. They don't do a hard review of it.

Q. And what experience do you have with Cook and Thurber doing an examination of a powdered infant formula plant?
A. With a specific Cook and Thurber audit doing a powdered infant formula plant?
Q. Yeah.
A. I don't think I've been there when they've --
Q. So zero?
A. Your words, yes, zero.
Q. You talked about Abbott having a liquid version of NeoSure; is that right?
A. Correct, correct.
Q. And you said that you thought it was inappropriate for a company with a liquid version of NeoSure to be involved in producing powdered NeoSure. Is that -- did I read that correctly?
A. That's essentially my opinion, yes.
Q. And your thinking there is that because you can get to commercially sterile in liquid form that you shouldn't be working with powder at all; is that right?
A. Correct.
Q. And until 2007 you worked at a company that made powdered infant formula; is that right?
A. Yes.
Q. And did you think it was immoral of the company to make powdered infant formula?

A. Excuse me?
Q. I'm sorry. Let me change the word. Did you think it was inappropriate that Wyeth had a product infant f -- or a -- in fact, strike that.
Wyeth made a powdered infant formula for preemies; right?
A. We made low-birth-weight powder, yes.
Q. And that was continuing up until the time you left in 2007?
A. It was. They were -- yes.
Q. Okay. And was it also inappropriate for Wyeth to be making powdered infant formula for premature infants?
A. I expressed that opinion.
Q. You expressed it inside Wyeth?
A. Oh, yes.
Q. But you continued to work and supervise that activity; right?
A. Well, we also had launched a product to make a liquid version of our LBW that was going to replace it.
Q. So is it okay for a company to have the powder if they don't have the liquid?
A. I just -- I don't think the powdered forms of this product are things that should be marketed, especially the way I know that they're marketed so . . .
Q. And until the time you became a consultant and were available to be testifying in things, you worked at a company

that made that kind of powdered infant formula including for premature infants; right?
A. Correct.
Q. And while you were working there, you personally believed that you had things working well enough so that you were a hundred percent sure that you never shipped infant formula with E. sak in it; right?
A. That would be my -- what I remember from my time there, yes.
Q. So it's not really inappropriate to be shipping a product that's a hundred percent sure not to have E. sak in it, is it?
A. Okay. I'm not exactly certain what the question is stating but --
Q. Well --
A. -- it sounds sort of okay.
Q. You said it was inappropriate for Abbott to be making and shipping a powdered infant formula because they had a liquid alternative; right?
A. Right, and that opinion's based on other things other than safety.
Q. I'm sorry. I thought it was related to safety. It wasn't related to safety?
A. It is related to safety, but there's other considerations as well.
Q. Okay. Well, sticking with the safety considerations, once

you're a hundred percent sure just on the safety aspect of why it's appropriate or inappropriate, once you're a hundred percent sure you're not shipping product with E. sak in it or other contam -- other pathogens in it, then it's okay to be shipping the product; right?

A. Yes.

Q. Now, you talked in your direct testimony about the inadequacies of Abbott's cleaning process; is that right?

A. Yes.

Q. And you also talked about the inadequacies of Abbott's //?

A. Your clean-in-place process is ////////////////////// no sanitizing rinse.

Q. Would you describe to the ladies and gentlemen of the jury what clean in place means?

A. Means that the equipment is cleaned without taking it apart, so you usually have pumps that force liquids at a relatively good pressure through nozzles so the inside of the equipment's sprayed. So typically you'll start out with caustic which is designed to get -- hot caustic which is designed to get the protein off the equipment, and you may or may not use acid every time, but the acid is designed to get minerals.

Q. Now, in the course of the testing of the production facilities at Abbott, do they test any areas that you did not test when you were at Wyeth?

A. I have no idea.
Q. Well, before you came here to criticize Abbott's testing processes, you studied them; right?
A. Their testing pr -- I've looked at their E. sak method, their salmonella method, what they do for environmental sampling. That's pretty much it.
Q. And so in that content then, just in those areas, does Abbott do testing that you didn't do at Wyeth?
A. We -- okay. The one test that we weren't doing was testing in the environment.
Q. How about spots that are tested? Did Abbott test places that Wyeth did not test?
A. I don't know. I don't have a complete list of the locations and where they went.
Q. What if we divide the world into contact and noncontact areas?
A. Okay.
Q. And by that, why don't we explain -- why don't you explain to ladies and gentlemen of the jury what we mean by contact and noncontact.
A. Well, the gentleman's trying to say product contact. So the idea is that you've got surfaces that are exposed to product and then you've got surfaces outside that that are not exposed to contact.
Q. And Abbott tests its product contact areas; right?

A. I'm assuming they do, yes.
Q. And Wyeth did not test their product contact areas; right?
A. Yes, we did.
Q. So you ran // -- or rather E. sak testing on your product areas?
A. Okay. You're --
Q. Product contact areas.
A. You're losing me here. Okay. So the --
THE COURT: Can we hold that thought till tomorrow morning at 8:30?
MR. REIDY: I'm sure we can, Your Honor. Thank you.
THE COURT: Would that be okay?
MR. REIDY: Thank you.
THE COURT: Thank you. Members of the jury, it's 2:30, so please keep an open mind. Don't read anything in the newspaper, and we'll see you back here at 8:30 tomorrow morning. Thank you.
(The jury exited the courtroom.)
THE COURT: Please be seated. Yeah, the witness can step down.
Mr. Reidy, about how much more time do you have on cross?
MR. REIDY: I was just discussing that with Mr. Rathke, Judge. I would say in the neighborhood of an hour and 15 or an hour and 30 and I'll be done. And I also promised

Mr. Rathke that I would work to make it shorter rather than longer.

THE COURT: Well, I appreciate that, and that's fine. You know, given the length -- you know, I kind of look at the length of direct, and yeah, I don't have any problem.

MR. REIDY: I'll certainly be in that parameter.

THE COURT: Sure. That's fine. You have a lot of material to cover.

Mr. Rathke, are your wheels turning on coming up with a plan, because at this rate we'll be well into February?

MR. RATHKE: Well, I . . .

THE COURT: You may be well into February. I won't be here. I mean, with all due respect, in 36 years in this business, I've never seen a lawyer take so long on direct examination of an expert. And if you think that's helping your case with the jury, I suggest I'd give you an enrollment to dental school at the University of Minnesota because it just isn't. So I don't know -- you know, I like to let lawyers try their case and all, but, you know, I made a commitment to the jury. And, you know, if I thought for a second that the examination except for Mr. Bottaro's which was right on point was going to be so convoluted, so poorly organized, and take so long, I would have had a chess clock out here so fast your head would be spinning. It just -- I've never seen anything like it in 36 years. I'm just telling you. Just -- as they say, just

sayin'.

So you can try it any which way you want. But, you know, you essentially told me you were going to get done by Friday. And at this rate it's going to be Friday, but it's going to be a week from this Friday. I don't even think you'd get done by then at this rate.

MR. RATHKE: I'm going to continue to try to cut this down and be as efficient as possible.

THE COURT: So are you still holding to your position you'll be done by noon on Monday?

MR. RATHKE: I think that that is possible, and that's -- that will be my goal from -- it has been my goal, and it will continue to be my goal.

THE COURT: Well, wait a minute. Your goal was to be done on Friday. That was your goal.

MR. RATHKE: But I never -- I always express -- you know, I never . . .

THE COURT: You always what? Excuse me? Well, I would think lawyers -- I would think lawyers would estimate on the high side or on the long side, particularly knowing I've got a complex patent case with all kinds of experts ready to go to trial the day this ends, and you knew that. So when you gave me the estimate you were going to be done by Friday, I took you at face value because I assume you estimate too long so that I'd be happy rather than, oh, gee, we're really not making progress,

because what judge gets happy about that?

Oh. So anyway, you know, it's hard to ask the defense how long you think your case is going to be because we have no idea when the plaintiff is going to be done, so, you know, this is a hypothetical. Well, do you think you can put your case on in five days? Is that what you're planning?

MR. REIDY: We are planning that, Your Honor.

THE COURT: Yeah, and that's what you told me originally, five days. Okay.

MS. GHEZZI: Your Honor, I just want to remind you.

THE COURT: Yes.

MS. GHEZZI: About on Monday we have the one Dr. Shulman who has to be done out of order.

THE COURT: Yes, yes, yes. No, that's fine.

MS. GHEZZI: Okay.

THE COURT: Yeah, I'll do everything I can to accommodate out-of-order witnesses. I always do in every trial. That's not a problem.

Okay. We'll see you tomorrow morning at 8:30. I'll just check with you a few minutes early. If anything comes up, let me know. We'll be here. So you need to come early or e-mail me. And we'll see you at 8:15 tomorrow morning. Thank you.

(The foregoing trial was adjourned at 2:36 p.m.)

CERTIFICATE

I certify that the foregoing is a correct copy of the transcript originally filed with the Clerk of Court on 3-20-14 incorporating redactions of personal identifiers and any other redactions ordered by the Court in accordance with Administrative Order 08-AO-0009-P.

S/Shelly Semmler — 4-29-14
Shelly Semmler, RMR, CRR — Date

INDEX

WITNESS:	**PAGE:**
JANINE JASON	
MS. GHEZZI	334
MR. RATHKE	388
SCOTT DONNELLY	
MR. RATHKE	392
MR. REIDY	474

*****